From: Bob Stock
Health Planning & Quality
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Minister for Health & Community Care

'HEPATITIS C FROM BLOOD' EX GRATIA SCHEME – DETAILS OF PROPOSED PARAMETERS AND ADMINISTRATION

Purpose

To seek Ministers endorsement of the detailed parameters that will apply to the scheme and for the proposals for administering it.

Priority

Immediate. Department of Health(DH) are proposing that there is a joint announcement by the four UK Health Ministers on either 18 or 19 December and Mr Chisholm will wish to inform cabinet colleagues before this.

Discussion

1. This minute outlines the proposals jointly agreed by officials of the Scottish Executive, DH, Welsh Assembly government and Northern Ireland administration. The basic parameters already announced in Scotland are retained (i.e. £20k basic award, £25k on reaching medical trigger, no payments to those who clear the virus spontaneously or to dependants of those who died before 29 August) but are augmented to cover detail on eligibility, supporting evidence and on how the scheme would be administered.

2. Proposed parameters are attached as Annex A, proposed administration as Annex B and commentary on both at Annex C. These are summarised at Annex D.

3. Officials in the other administrations will simultaneously be submitting minutes to their Health ministers making the same proposals. It is expected that John Reid, Secretary of State, will then contact the other Health ministers to seek agreement to the proposals and the date and content of a joint announcement.

4. Following on the announcement, work will proceed to establish the administration of the scheme and to amend social security regulations and regulations that apply to housing improvement and repair grants and to residential care charging. Once the scheme administration has been established and legislative changes are in hand, it is proposed that there will be a high profile media initiative to inform potential beneficiaries as to what they need to do to apply for awards. This will be backed up by proactive approaches to people are very likely to have been infected (including all haemophiliacs) and to people who have already registered an interest.

Recommendation

5. **That Ministers endorse the attached proposals for administering the scheme and for the detailed parameters that will apply to it.**

BOB STOCK
Health Planning & Quality, 46913 12 December 2003

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
First Minister					X
Deputy First Minister					X
Minister for Finance and Public Services					X
Minister for Parliamentary Business					X
Deputy Minister for Parliamentary Business					X
Deputy Minister for Health & Community Care					X

PS/Perm Sec

Cabinet Secretariat

PS/FCSD

PS/HD

Andrew Baird, Head of Press

Press First Minister

Press Health

Jeane Freeman, Senior Special Adviser

Sam Ghibaldan, Senior Special Adviser

Douglas Campbell, Senior Special Adviser

Matthew Clark, Special Adviser

Liam McArthur, Special Adviser

Policy Unit

PFO

Lord Advocate

CMO

David Palmer, Directorate of Performance Management & Finance

Dr Peter Collins, Directorate of Performance Management & Finance

Dr Aileen Keel, DCMO

Ian Gordon, Directorate of Service Policy & Planning

Andrew MacLeod, Health Planning & Quality

Colin Miller, Constitution Unit

Jan Marshall, OSSE

Peter Stapleton, Community Care Charging

Jean Waddie, Development Department (Housing Division)

ANNEX A

'HEPATITIS C FROM BLOOD' EX GRATIA SCHEME – DETAILS OF PROPOSED PARAMETERS AND ADMINISTRATION

PROPOSED SCHEME PARAMETERS

Eligibility date

- No payments will be made in respect of people who died before 29 August 2003.
- Where people die before the scheme is in a position to make payments, and their circumstances and medical condition would have satisfied the eligibility criteria on 29 August 2003, then the awards will be made to their dependants.
- Once the scheme is in a position to make payments, then awards will only be made in situations where a claim has been received from the infected person. If the infected person dies without making a claim then an award will not be made to their dependants.

Eligibility for Basic Award of £20,000

Criteria

- Potential beneficiaries will receive the basic award of £20,000 if they have been infected with Hepatitis C as a result of being provided by the NHS with blood or blood products before September 1991.
- People who have been infected with Hepatitis C as a result of the virus being transmitted from a person who themselves was infected as a result of being provided by the NHS with blood or blood products before September 1991 will be treated identically to those directly infected.
- People who have received payments from the Macfarlane Trust, Eileen Trust or Special Payments Scheme in respect of infection with HIV, and who have also been infected with Hepatitis C, will be treated identically to those who have only been infected with Hepatitis C.

Required supporting evidence

- Claimant received relevant treatment – *statement by clinician*
- Claimant infected with Hepatitis C – *statement by clinician*
- People who have had a liver transplant – *would only need to establish that they had originally been infected with Hepatitis C, not that they are still infected.*
- People who have cleared the virus as a result of treatment – *would only need to establish that they had originally been infected with Hepatitis C, not that they are still infected.*

- The Hepatitis C infection was caused by the NHS treatment:
  - For people who have received a pooled product – *statement by clinician confirming that the claimant had tested PCR positive would suffice as proof of causation.*
  - For other people – *causation should be corroborated by reference to archived samples where these are available.*
- Where definitive evidence on any of the above is lacking, then such evidence as does exist should be accepted if it establishes the facts "on the balance of probabilities".
- "Balance of probabilities" should be determined by reference to general rules set down by an appointed independent panel or, where more appropriate, decided by the panel on a 'case by case' basis.

Eligibility for additional payment of £25,000

Criteria

Potential beneficiaries who satisfy the basic eligibility criteria will receive the additional award of £25,000 when it is established that they have cirrhosis, liver cancer or have received a liver transplant.

Required supporting evidence

- cirrhosis:
  - liver biopsy results (if already carried out in the course of normal treatment), OR
  - results of non-invasive tests (as specified by hepatologists expert group) that have been carried out in the course of normal treatment.
- liver cancer – statement by clinician
- liver transplant – statement by clinician.
- in the event that doubt still remains about any relevant medical aspect, then an appointed expert medical panel will adjudicate on a 'case by case' basis – using the "on the balance of probabilities" principle.
- the medical panel may commission additional non-invasive tests specifically for the purpose of informing their judgement.

Exceptions to the general scheme parameters

- People who have cleared the virus spontaneously will not be eligible for either the £20,000 or the £25,000 award.
- People who have received a liver transplant will receive both the basic and additional awards.

Variations to awards

- People who have received compensation as the result of a successful legal action against the NHS (or an out of court settlement in relation to a legal action) in respect of a situation satisfying the basic eligibility criteria for this scheme would have that compensation/settlement deducted from the total award made under this scheme.
- People who have received compensation as the result of a successful legal action against a product supplier in respect of a situation satisfying the basic eligibility criteria for this scheme, would have that compensation deducted from the total award made under this scheme.

Conditions attached to awards

- People who receive payments under the scheme would undertake not to institute future legal proceedings against the NHS or Ministers in relation to the situation that formed the basis of those payments.

Lifetime of scheme

6. Given that it may take 20-30 years for Hepatitis C infection to progress to the stage where the additional £25,000 payment would be made, it will be necessary to maintain the capability to make payments under the scheme for at least another 20 years and probably longer – although the number of payments in the latter years will be very small.

ANNEX B

'HEPATITIS C FROM BLOOD' EX GRATIA SCHEME – DETAILS OF PROPOSED PARAMETERS AND ADMINISTRATION

PROPOSED ADMINISTRATION ARRANGEMENTS

Single UK scheme

1. It is proposed the four UK administrations operate essentially identical schemes with identical awards and that the most efficient way of dealing with this is for payments on behalf of all four administrations to be handled as part of a single UK scheme –administered by a single independent Trust.

2. It has been suggested that this might be named Skipton Trust. The basis for this is that the substantive negotiations between officials of the four administrations took place in Skipton House, London. This would continue the precedent set by the Eileen Trust which was named after Eileen House.

3. The Macfarlane Trust has agreed to take on the task of setting up and administering the new Trust.

Financial arrangements

4. The four administrations would be billed by the Trust for awards paid out to beneficiaries attributable to the relevant country. The logical method of attribution would be that the beneficiary had been infected as a result of treatment in that country. An alternative would be that the beneficiary was currently resident in that country. This alternative method would only be acceptable if significant savings in administrative process were likely and estimates showed that the method would not materially alter the split between the four countries.

5. Department of Health would take the lead in dealing with the new Trust. The four administrations would contribute to the establishment and running costs of the Trust and possibly also to an initial working capital fund. It is likely that the basis for these contributions would be the population ratios between the countries.

Verification of claims

6. Claimants would be asked to submit evidence in support of their claims via a standard form – which would be vetted as a clerical exercise and, where appropriate, corroborative evidence (such as archived specimens) accessed and checked.

7. An independent panel (or possibly two separate panels) would decide on medical and non-medical evidence where it was not straight forward.

ANNEX C

'HEPATITIS C FROM BLOOD' EX GRATIA SCHEME – DETAILS OF PROPOSED PARAMETERS AND ADMINISTRATION

KEY ISSUES

Sensitivities

1. The Haemophilia Society has been made aware of the likely scheme parameters and believes them to be unacceptable. This is principally because they feel the awards are too low and because no payments are to be made to the dependants of those who died before 29 August. Payments to dependants of the deceased were included in their own proposals to DH, in the recommendations of the Expert Group to the Scottish Executive, and the MacFarlane and Eileen Trusts made such payments.

Financial Implications

2. Statistical estimates indicate that 1165 people infected in Scotland might still be alive. It is assumed that 580 of these would come forward within the first 3 years of the scheme – requiring an outlay by the Scottish Executive of £15m on awards. In the unlikely event that all the 1165 claimed the eventual cost to the Scottish Executive of making awards would be £30m. These estimates exclude cost associated with awards to those contracting the virus from someone who was themselves infected via blood or blood products, but these are thought to small.

Presentation and Parliamentary Implications

3. In the event that all four UK Health Ministers agree that the scheme should proceed on the basis described, then Press Health and special advisers will need to liaise urgently with the other administrations (particularly Department of Health) to develop a common approach to the media. This approach should attempt to emphasise positive aspects (compassionate gesture, non-bureaucratic path for making claims, independent nature of administration and scrutiny arrangements) whilst recognising that challenges will be made regarding award levels being too low and dependants of the deceased being excluded.

4. These challenges may be also be made in the Scottish Parliament. However, the Health and Community Care Committee has recently decided that it does not intend to pursue the 'HCV from Blood" issue any further unless new evidence comes to light. The Committee's decision includes an acceptance of the broad parameters of the ex gratia scheme as already announced – including the level of awards and the decision not to make awards to the dependants of those who have died before 29 August 2003.

Legislative Implications

5. Existing statutory provision may be adequate to enable payments to be made on behalf of the Scottish Ministers. However, if this proves not to be the case, non-statutory

powers would be available to allow Scottish Ministers to make payments of the sort contemplated in advance of any new primary legislation being enacted.

6. DH advise that Department of Work and Pensions (DWP) have agreed to amend their social security legislation so that beneficiaries of the scheme will not lose means tested benefits. The amended legislation will come into effect in April 2004. Residential care charging regulations will be amended at the same time. Regulations on housing improvement and repair grants will also need to be amended so that payments to beneficiaries of the scheme are excluded from means testing.

Consultation

7. OSSE, Performance Management and Finance, Constitution Unit, Dr Keel (DCMO), Press Health, Community Care Charging, Development Department (Housing Division) have been consulted on relevant aspects of this submission.

Commentary on scheme parameters

Underlying philosophy

8. The underlying philosophy spelled out in previous public statements in Scotland is that establishment of the scheme is as follows:

- This is a compassionate gesture – not a tacit acknowledgment of liability or wrong doing.
- As such, awards are ex gratia payments – not compensation.
- Expenditure on scheme has to be balanced against the needs of other healthcare priorities (and the needs of other patients).
- This means only limited funding can be spared.
- Within the constraints of limited funding, the people who should be targeted for financial assistance are those who are still alive and suffering the adverse effects of being infected with Hepatitis C.

Medical trigger for additional £25,000 award

9. Expert hepatologists took the view that the stages of liver damage preceding cirrhosis were difficult to assess with non-invasive tests. Decompensated cirrhosis was easy to assess but by the time this stage had been reached life expectancy was low. Cirrhosis at the stage prior to decompensation therefore offered the best option for the medical trigger.

10. The experts believed that a number of non-invasive tests that are routinely carried out as part of normal treatment regimes could provide useful evidence of cirrhosis. In most cases combination of the results from a number of such tests would be sufficiently conclusive for the purposes of the scheme. This would avoid a situation where invasive liver biopsies (carrying a high risk for haemophiliacs) need to be conducted specifically to establish eligibility.

Co-infection with HIV

11. SCIEH report that 6.9% of those people infected with Hepatitis C via blood in Scotland who are still alive are co-infected with HIV. These people will have received payments from either the Macfarlane or Eileen Trusts in relation to their HIV infection. Experts do not believe that co-infection of itself results in significant additional suffering, but the treatment for Hepatitis C has more debilitating side effects than the treatment for HIV.

12. Macfarlane Trust has made it a condition of their involvement in scheme administration that their registrants are treated identically under the scheme as those only infected with Hepatitis C and John Reid, SoS Health, has indicated that England is prepared to concede this point.

Clearing the virus under treatment

13. Experts do not believe that people who have cleared the Hepatitis C virus under treatment continue to experience any residual ill health as a result of their infection. They do carry a small increased risk of liver cancer, but in the event that this was realised they would be eligible for the additional £25,000 award.

14. These people will have experienced past suffering as a result of their infection and the treatment, but this does not satisfy the underlying principle of the scheme to target those currently suffering. However, making them ineligible for the basic award would create an anomaly. This is because some people might receive the basic award and then subsequently clear the virus under treatment – putting them at an advantage over those who cleared the virus before the scheme cam into operation. It might also lead to people refusing treatment until after they had received the basic award. John Reid, SoS Health, has indicated that England is prepared to pay this category of patient.

Commentary on standard of evidence

15. The passage of time since the original infection means that potential beneficiaries face real problems in producing irrefutable evidence. In particular, clinicians who treated them may be retired or deceased, and hospitals may have difficulty in finding their medical records or may have legitimately destroyed them. In recognition of this it is proposed that the lower standard of "on the balance of probabilities" (rather than "beyond reasonable doubt") is adopted for evidence.

16. It is certain that virtually all blood products produced from pooled donations will have been infected with Hepatitis C. It is proposed that where claimants have received such products then no further evidence will be required to establish that they were infected via blood products. Virtually all haemophiliacs will fall into this category.

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ANNEX D

'HEPATITIS C FROM BLOOD' EX GRATIA SCHEME – DETAILS OF PROPOSED PARAMETERS AND ADMINISTRATION

SUMMARY

Eligibility and awards

- £20,000 to people who were infected with Hepatitis C as a result of being provided by the NHS with blood or blood products before September 1991.
- £20,000 to people who have been infected as a result of the virus being transmitted from a person who themselves was infected as above.
- Additional £25,000 to people who are eligible for the £20,000 award when their condition progresses to cirrhosis, liver cancer or if they have received a liver transplant.
- No payments to those who have cleared the virus spontaneously.
- People co-infected with HIV will be dealt with in the same way as those infected only with Hepatitis C.
- People who have had a liver transplant will receive both the £20,000 and £25,000 awards.
- People who have cleared the virus under treatment will be dealt with in the same as those who still have the virus.

Payments to the 'deceased'

- No payments to dependents of people who died before 29 August 2003.
- Where people eligible on 29 August 2003 die before the scheme is in a position to make payments, awards will be made to their dependants.
- Once the scheme is in a position to make payments, awards will only be made to dependants where a claim has been received on behalf of the infected person prior to their death.

Variations and conditions

- People who have received compensation as the result of a successful legal action against the NHS (or an out of court settlement in relation to a legal action) would have that deducted from the total award.
- People who have received compensation as the result of a successful legal action against a product supplier would have that deducted from the total award.
- People who receive payments under the scheme would undertake not to institute future legal proceedings against the NHS or Ministers in relation to the situation that formed the basis of those payments.

Evidence

- Generally evidence will be judged on the balance of probabilities.
- It would be presumed that claimants with Hepatitis C who have received pooled products were infected by the product. (Virtually all haemophiliacs will fall into this category).
- No requirement for invasive tests to establish cirrhosis.

Administration

- Single UK scheme operating to common parameters in Scotland, England, Wales and Northern Ireland.
- Administered by a single independent charitable Trust.

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