Falconer S (Sandra)

From: Stock RG (Bob)
Sent: 06 August 2003 09:46
To: Minister for Health and Community Care
Cc: First Minister; Deputy First Minister & Minister for Enterprise; Deputy Minister for Health and Community Care; Gordon IW (Ian); PS/HD Health; Marshall J (Jan); Palmer DJ (David)(Health Finance); Keel A (Aileen); Macleod AK (Andrew); Freeman J (Jeane); Lord Advocate; Falconer S (Sandra)
Subject: 'HCV from blood' ex gratia payment scheme

Please find attached submission on the above (10 pages including annexes)

Private Secretaries please note: the content of this submission is highly sensitive and the UK government has asked that knowledge of it is restricted to the minimum number of personnel - on a strictly 'need to know' basis

Bob Stock
Health Planning & Quality
GRO-C

DH HCV discussions.doc

Reveals: (SOME PRESS ?)
• Wales + NI not 'properly' informed
• Discussions on timing/Wales between Reid/Ulrichsen

GRO-C

From: Bob Stock
Health Planning & Quality Division

Minister for Health & Community Care

EX GRATIA PAYMENT SCHEME FOR 'HCV FROM BLOOD' PATIENTS

Purpose

1. a] To provide briefing on discussions at official level between the Executive and the Department of Health (DH); b] to seek Ministers' views – especially on the establishment of a UK scheme.

Priority

2. Routine – but if Ministers have concerns about any aspects of the discussions then the it is important they are registered as soon as possible.

Summary

3. A letter of 28 July from John Reid, Secretary of State for Health, to Malcolm Chisholm confirmed that the Executive's proposed scheme was accepted by the UK government as within devolved competence. It invited discussions at official level to explore the potential for similar types of scheme elsewhere in the UK and how the scheme would fit within the benefit system.

4. Initial discussions on 30 July showed that DH officials are interested in operating an identical system in England sharing the proposed Scottish formula i.e. initial payment of £20k plus an additional £25k on reaching a medically defined trigger point – payments only to those alive when the scheme is launched and who have not cleared the virus spontaneously.

5. DH officials favour establishment of a single charitable Trust that would administer payments on a UK basis – billing administrations according to where claimants were infected. They have spoken with DWP and believe it would be a simple matter to obtain a social security disregard for payments from such a scheme

6. DH officials are tasked with submitting options and recommendations to SoS Health by 29 August with the intention of making a joint announcement in the autumn. The DH proposals mentioned are still at a preparatory stage and are all subject to agreement by SoS. Allowing for refinement of details, secondary legislation for social security disregard, and establishment of the charitable Trust and associated panels, payments could commence in early Spring 2004.

7. UK government special advisers will draft a new line that can be used in the meantime e.g. by Malcolm Chisholm at his appearance before the Health Committee on September 9, and will submit this to the Executive for comment.

8. Areas under discussion with DH are listed and briefly discussed in Annex B. A DH note of the initial meeting is attached as Annex C.

Conclusion

Ministers are invited:

a] to indicate whether they are content for discussions to proceed on the basis that a UK scheme, administered by a single charitable Trust, be established

b] to express any concerns/views they have about any other aspect of negotiations with DH

Bob Stock, Health Planning & Quality Division, 46913 6 August 2003

Copy List:	For Information [General Awareness]
First Minister Deputy First Minister Deputy Minister for Health & Community Care	X

Ian Gordon (Service Policy & Planning) PS HD Andrew MacLeod (Health Planning and Quality) David Palmer (Finance & Performance Management) Jeanne Freeman (Policy Unit) Jan Marshall (OSSE) Dr Aileen Keel (DCMO) Lord Advocate

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ANNEX A

EX GRATIA PAYMENT SCHEME FOR 'HCV FROM BLOOD' PATIENTS

KEY ISSUES

Issues under discussion with DH

1. The following issues are under discussion:

- Holding line
- Scheme administration
- Eligibility criteria
- Acceptable levels of evidence
- The medical trigger to be used for the additional £25k payment
- Appeals procedures

Sensitivities

2. DH are very concerned that the developments described in this minute do not leak out prior to the joint ministerial announcement in the autumn. They have asked that information is promulgated to the absolute minimum number of personnel necessary to enable the matter to be taken forward. At this stage neither the Welsh or Northern Ireland administrations are party to developments.

3. DH believe the proposal not to make payments to the dependants/relatives/estates of deceased patients may well be contentious. Although they accept that costs could increase uncontrollably if this approach is not adopted, they are concerned that lobbying by NGOs in England could adversely affect the launch of the scheme.

Financial Implications

4. On the basis of current information, refinements to the scheme parameters e.g. the medical trigger for the additional £25k payment, are not expected to significantly change the cost estimates that formed the basis of previous Ministerial decisions.

Presentation and Parliamentary Implications

5. To be developed once the scheme parameters and administration have been agreed and a definitive timeline established.

Legislative Implications

6. None.

Health Planning & Quality
6 August 2003

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ANNEX B

EX GRATIA PAYMENT SCHEME FOR 'HCV FROM BLOOD' PATIENTS

KEY POINTS UNDER DISCUSSION WITH DH

Holding Line

1. DH are anxious that any new line made public prior to the joint Ministerial announcement in the autumn does not indicate that a Scottish scheme will definitely go ahead. We have emphasised that the Executive is going to come under intense pressure once the Scottish Parliament reconvenes – and particularly at Malcolm Chisholm's appearance before the Health Committee on September 9.

2. We have suggested that it would be helpful if the line could indicate that it had been agreed by the UK government that the proposed Scottish scheme was within devolved competence but that discussions were continuing to establish the position on the scheme's effect on social security payments. This would of course give rise to pressure for the Executive to enter into bilateral talks with DWP.

Scheme administration

3. DH officials favour asking the Macfarlane Trust to establish and administer a new charitable Trust to deal with payments to 'HCV from blood' patients (in the same way as they established the Eileen Trust to make payments to patients who had contracted HIV from blood transfusions). The new Trust would effectively operate a UK-wide scheme. Common scheme parameters would apply – except that the dates when the various blood products were made HCV-safe in Scotland would be different to those in England. The Trust would bill Scotland according to the outgoings associated with the 'Scottish' claimants and there would be some agreed mechanism for sharing administration costs.

4. The alternative would be for Scottish arrangements to be kept completely separate e.g. by having payments made to 'Scottish' claimants via a Scottish charitable Trust. Use of Macfarlane on a UK-wide basis is likely to be a quicker and cheaper option. It may also prove easier to obtain a social security disregard in respect of a charitable Trust that is operating across the entire UK.

Eligibility criteria

Basic eligibility

5. Basic eligibility criteria would be that the claimant had contracted the Hepatitis C virus as a result of having received blood, blood products or tissue from the NHS before arrangements were in place to make these HCV-safe. The basic payment would be £20k.

Additional payment

6. This would be paid to claimants who had satisfied the basic eligibility criteria and whose condition had deteriorated to a point defined by an agreed medical trigger point. The additional payment would be £25k.

Exceptions/variations

7. It is suggested that the following would apply:

- People who had cleared the virus spontaneously would not be eligible for any payment.

- People who have received payments linked to HIV infection from the Macfarlane Trust, Macfarlane Special Payment Trust, Eileen Trust or the associated government Scheme of Payments, shall not be eligible for the basic payment. They will receive the additional payment if they reach the defined trigger point.
- People who clear the virus under treatment shall only receive the basic payment.
- People who receive a liver transplant shall receive both the basic and the additional payment.
- 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, shall 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, shall have that compensation deducted from the total award made under this scheme.
- People who receive payments under this scheme shall undertake not to institute future legal proceedings against the NHS or Ministers in relation to the situation that formed the basis of those payments.
- No payments shall be made to the relatives, dependants or estates of eligible claimants who are deceased at the time the scheme becomes operative (this approach would mark a change in precedent, as similar Trusts do compensate the 'personal representative' of eligible deceased patients).
- Payments might need to be considered for infected intimates.

Medical Trigger for the additional payment

8. Since the Scottish proposal was made public we have become aware of significant drawbacks to using cirrhosis as the medical trigger. DH accept this view and do not favour either liver cancer or liver failure as triggers. We have suggested that it might be possible to agree an 'advanced liver inflammation' definition that could be used for the trigger – based on various non-invasive techniques. There would need general agreement to these by with medical experts – including experts acceptable to the Haemophilia Society.

9. The proposed trigger would exclude some people with cirrhosis who would not suffering as a result of the condition. It would include some people who have not reached the cirrhosis stage. We need to estimate the nett financial implications of this proposed change – taking into account the refinements to the eligibility criteria listed in the previous section.

Acceptable evidence

10. This represents one of the most difficult areas under discussion. The scheme could demand irrefutable evidence that the HCV infection arose from NHS treatment. This would include a statement from the claimant's clinician stating their current medical status and that they had received relevant treatment. The claimant's medical records would then be used to access the batch numbers of the material believed to be the cause of infection. In the case of SNBTS material, archived specimens could be checked to establish whether they contained the Hepatitis C virus. In the case of commercial material, archived samples are not available and HCV contamination might have to be assumed.

11. There are a number of difficulties in requiring this level of evidence. We know there have been difficulties with patients accessing their medical records and batch numbers from

the 1980s – when infection will have occurred. There may also be difficulties due to the retirement or death of the clinician concerned.

12. In such circumstances there is an argument for giving claimants the benefit of the doubt. At its most extreme this could extend to the approach recommended by the Expert Group i.e. claimants would only have to demonstrate, on the balance of probabilities, that they received relevant material from the NHS before arrangements were in place to make it HCV-safe – and that they subsequently contracted HCV.

13. This 'benefit of the doubt' approach requires no direct proof of a causal link, and there is a view that it would be open to abuse i.e. people could successfully claim who had contracted HCV from another source than NHS 'blood'. The main source of HCV infection other than blood is drug abuse and the risk to the scheme might be limited by requiring claimants who cannot produce irrefutable evidence to certify that they have not been involved in drug abuse and to have this corroborated by their clinician. However, there are limits to how effective this might be and there may be sensitivities about stigmatising drug abuse.

14. Only a proportion of drug abusers are likely also to have received 'blood' in the relevant time frame. It is possible to envisage situations however where people may claim they had relevant treatment that was not recorded or may falsely claim they had relevant treatment when they know this cannot be corroborated because their medical records have been lost/destroyed.

Appeals

15. We believe it would be necessary to establish a medical panel. This would rule on issues such as whether or not marginal cases met the medical trigger definition. We also believe there should be a lay tribunal that would rule on other issues – notably cases where 'benefit of the doubt' is claimed under circumstances that are marginal for any general rules that have been agreed.

Health Planning & Quality
6 August 2003

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ANNEX B

EX GRATIA PAYMENT SCHEME FOR 'HCV FROM BLOOD' PATIENTS

DH NOTE OF OFFICIALS MEETING 30 JULY 2003

Ex gratia payments to patients who were infected with Hepatitis C as a result of NHS treatment with blood or blood products

Notes of a meeting held on 30 July 2003

Present Andrew MacLeod (Scottish Executive)
Bob Stock (Scottish Executive)
Richard Gutowski (DH)
David Reay (DH)

Brief background

Following the decision by the Scottish Executive to make ex gratia payments to patients in Scotland infected with Hepatitis C via contaminated NHS blood and blood products before the introduction of heat treatment/screening, and subsequent to correspondence between the Minister for Health in Scotland and the Secretary of State for Health, a meeting was convened to discuss DH collaboration on this issue.

Salient issues

It was agreed that the following issues required resolution before work on a compensation scheme could begin –

- Scope. Rather than individual provincial schemes, a UK wide scheme was favoured by both the Scottish Executive and DH. This would be easier to administer, ensure equity and precedents were already in place.
  Action – the scheme will be developed on this basis, subject to Ministerial approval.

- Devolution. Although the Scottish scheme is within devolved competence, the position with regards to Wales and Northern Ireland is less clear. If a UK wide scheme is developed, its jurisdiction in the devolved provinces will need to be clarified and mechanisms of joint funding defined. Wales and NI are not aware of developments so far and a decision about the timing of their involvement is yet to be taken. Concerns were raised that there may be a legal obligation to share information.
  Action – lawyers from both DH and the Scottish Executive will be asked to provide guidance on financial, legal and constitutional issues with a view to seeking Ministerial approval of a UK wide scheme and a decision as to when to involve Wales and NI.

- Scotland. The Minister for Health in Scotland is under pressure from the Scottish Parliament to make an announcement as to when a compensation scheme will be established in Scotland. In view of SofS's request for solidarity, the Scottish Executive has asked DH for a holding line to ensure consistency and for the Minister for Health's Parliamentary Committee appearance on 9 September.
  Action – A revised line is being drafted by DH special advisers and this will be shared with Scotland. The Executive feels it is important this reflects a positive/progressive position.

- Finance. Estimates of the potential cost of a scheme have been prepared for England and Scotland but resources have not yet been identified in England. The implications of funding claims in Wales and Northern Ireland are also still being considered.
  Action – Finance division in DH is exploring options to secure resources.

Proposed parameters of the scheme

1. It was felt that the scheme should be administered independently and that Government should be distanced from the disbursement process. Two options were proposed on how the scheme might be developed. The first was to establish a scheme under the umbrella of the Macfarlane Trust, a UK arms-length body compensating haemophiliacs who have contracted HIV via contaminated NHS blood and blood products. The second was to constitute an entirely new trust as was done for the vCJD compensation scheme.

2. The former option was preferred for reasons of simplicity and because of the successful management of the Macfarlane Trust. It was thought that the Macfarlane Trust would be amenable to this proposal, especially as it already administers the smaller Eileen Trust (which provides payments to non-haemophiliacs who have contracted HIV via NHS blood and blood products). The Eileen Trust could serve as a model for the new scheme.

3. An eligibility criterion for awards and the extent of supporting evidence submitted need to be determined. Where it exists, it is envisaged that claimants will generally be given the benefit of the doubt (eg. because of lost/destroyed medical records etc). But it is not expected that relatives, dependants and/or the estates of patients who have died will receive payments, even if they died between the announcement of the scheme and its launch. This approach would mark a change in precedent, as similar Trusts do compensate the 'personal representative' of eligible deceased patients.

4. The level of awards would be based on the Scottish model already speculated to the Scottish Parliament. Those qualifying would receive a £20,000 payment, followed by a further £25,000 should their disease progress to a medically defined trigger point. Medical advice will be sought to provide a clear definition of the trigger. Estimates suggest that the cost of such a scheme in England alone would be around £210m.

5. The initial £20,000 payments would not be made to patients who are co-infected with HIV and who have received awards from other Government sponsored schemes such as the Macfarlane Trust. However, this group would be eligible to claim the £25,000 award should their condition progress to the trigger point.

6. Eligible patients who cleared the disease spontaneously (approx 20%) would receive no payments, those who cleared after treatment would receive the £20,000 payment only and those who receive a liver transplant would receive both awards. Those patients eligible for awards who had successfully sued the NHS or private supplier or reached an out of court settlement, would have the settlement deducted from the amount awarded by the proposed scheme.

7. Following preliminary discussions with DWP and according to Inland Revenue precedents, it is envisaged that awards will be disregarded in respect of social security payments and income tax contributions. Macfarlane Trust awards are already disregarded and although social security disregard requires amendment to legislation, DWP advice suggests this is a

simple process. Disregard for income tax purposes would require an amendment to the IR's General Rules, but not legislation.

8. The constituting of a trust would require the appointment of trustees and inclusion of an appeals process. Trustees would most likely be appointed directly by SofS in consultation with Ministers from the devolved administrations and by voluntary organisations with an interest (eg. the Haemophilia Society). Demographic make-up would be an important consideration. DH is seeking legal advice as to whether a formal appeals process is necessary.

Issues arising from the Scottish Executive proposals

The following action was agreed –

- DR to collect relevant figures for haemophiliacs in England and dates of introduction of screening and heat treatment etc of blood in England and liase with Finance in respect of awards made based on these figures
- DR to also collect figures for Wales and NI (pending legal advice on whether an ex gratia payment scheme is a devolved issue)
- DR and BS to obtain medical advice re. definition of medical trigger of 2nd payment and then provide estimates of (or confirm) numbers progressing to this stage
- DR and BS to seek medical and policy advice on extent of supporting evidence supplied by claimants and present options
- DR to consider implications of potentially contentious proposals (such as not making awards to 'personal representatives' of deceased patients, payments to co-infected patients and those who have been treated for Hep C)
- DR to forward note of discussions with Dept of Health lawyers to BS
- DR to confirm DWP disregard position with regards to Scotland post-devolution
- DR to begin work on UK discussion paper that will highlight areas requiring Ministerial decisions
- DR and BS to ensure Malcolm Chisholm is informed of developments in England and has a consistent line to take for his appearance in front of the Scottish Parliamentary Health Committee on 9 September and to keep SofS updated
- DR to ensure that SE request for a positive/pro-active stance is reflected in the line to take

Next steps

- A constructive dialogue has now been opened between DH and Scottish Executive officials. This will ensure the sharing of information, co-operation and consultation between our two Departments to aid a joint approach.

- The discussion paper tabled by the Scottish Executive will be expanded to make provision for a UK wide scheme. This will outline the development process and structure of the proposed scheme and form a basis from which an announcement can be made and scheme rolled out.

- The scheme will be advanced as above subject to the resolution of the issues laid out at the start of this note. A rough timetable would see –

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- an update to SofS on 29 August suggesting ways forward (in association with briefing for the Minister of Health in Scotland for his appearance in front of the Scottish Parliament's Health Committee on 9 September);

- then a decision shortly afterwards by SofS to inform Wales and NI of the scheme and invite them to join;

- followed by Treasury agreement and a joint Administration announcement of the scheme in the Autumn and

- the commencement of a scheme in the Spring.

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