Stock RG (Bob)

From: Stock RG (Bob)
Sent: 21 November 2001 10:39
To: Minister for Health and Community Care; Deputy Minister for Health and Community Care
Cc: Minister for Parliament; Minister for Social Justice; PS/HD Health; PS/Perm Sec; PS/FCSD; MacMahon P (Peter); Currie CT (Colin); Ghibaldan S (Sam); Hamilton FM (Fiona); McTernan J (John); Policy Unit; McCroskie J (John); Wyeth C (Kit); Whittle P (Pam)
Subject: DRAFT CABINET CORRESPONDENCE AND RESPONSE TO H&CCC COMMITTEE REPORT ON HEP C

Importance: High

Further to my submission of 16/1, I now attach a second draft of the cabinet correspondence (including the draft response to the Committee's report on Hepatitis C).

This version incorporates comments received from consultees. Where these comments were straightforward I have amended the text in the draft. Where the comments raised issues which were not resolved, I have presented the issue in bold & italic font between square brackets. [If it would be helpful for you to see a version where all the changes are presented in tracked form please let me know].

I should be grateful to receive your comments by 1000 tomorrow (22/11). I will then incorporate them and send the final version to Private Office for onward transmission to cabinet. **That would allow cabinet 4 and a half working days to respond to the First Minister** (30/11 being the last day we have to compile the final response before the December 3 deadline).

Please note that in my submission I incorrectly stated that Mr Beaton's responsibility was 'Social Justice' whereas it is in fact 'Civil Justice'.

Bob Stock
Health Planning & Quality
GRO-C

Cabinet Corresp
Comments2.doc

Susan Deacon
22 November 2001

DRAFT 2

First Minister

Copy to: Cabinet Ministers
Deputy Minister for Health & Community Care
Heads of Department
Mr J McTernan - Head of Strategy
Mr S Ghibaldan - Special Adviser
Policy Unit
K Wyeth, ES Cabinet Secretariat

CABINET CORRESPONDENCE: RESPONSE TO THE HEALTH AND COMMUNITY CARE COMMITTEE'S REPORT ON HEPATITIS C IN BLOOD

Purpose

1. To seek agreement to the Scottish Executive's formal response to the recommendations made in the Health and Community Care Committee report "*Report on Hepatitis C*".

Priority

2. Urgent. The deadline for the Executive's response to reach the Committee is 3 December. Comment should therefore be sent to the First Minister to arrive no later than close 28 November.

Background

3. The Committee's direct involvement in this issue arises from their consideration of two petitions. One petition called for an independent enquiry into the contamination of blood products for haemophiliacs with Hepatitis C. The other called for Parliament to set up a compensation scheme for all those infected with Hep C through contaminated blood transfusions.

4. The Committee rejected the call for an independent enquiry. They also found NHSScotland blameless on number of other counts ie negligence in relation to the introduction of screening and deliberately withholding risk information from patients.

5. However, they accepted the call for compensation and made recommendations as to how this should be carried out. The Committee also made additional recommendations that went beyond the scope of the petitions.

6. The Committee's recommendations in full are detailed in Appendix A. In summary they cover the following areas:

a] Provision of financial and practical support to all people who have contracted Hep C. This support to be available regardless of whether negligence or Consumer Protection Act (CPA) liability exists. The mechanism for providing support to be determined in consultation with sufferers and to be operational within 12 months.

b] Investigation into the adequacy of advice given to patients about the risks of receiving blood products.

c] A protocol requiring the Executive to consult the Committee on the terms and membership of any internal enquiry team.

d] A commission to examine the current system of negligence and fault-based compensation.

7. The Executive's current policy is not to pay compensation when there is no legal basis for NHSScotland being found at fault. Cabinet confirmed this policy at its July 10 meeting – – Paper No.SC(80). Following the Burton judgement in the English High Court the Executive has instructed NHSScotland solicitors to seek settlement with those people who have raised legally competent actions under CPA that are analogous with the Burton judgement.

8. This excludes all people who were infected before 1st March 1988 and many who were infected after that date who are unable to raise legally competent actions because of time bar constraints

Discussion

9. Full text of the proposed response to the Committee is attached as Appendix B. Particular aspects of the response are discussed below.

Support for Hep C sufferers

10. The Committee claims that it supports the general principle of not paying compensation for harm caused by NHS treatment "simply because the treatment carried a risk, and that risk subsequently crystallised as an injury". It agrees that a "risk-averse NHS is in no-one's interests" and says it is not asking the Executive to "establish any new, wide-ranging precedent on the management of risk in clinical decision-making".

11. The Committee argues that it is simply seeking to correct an inconsistency in the operation of the "narrow" precedent created by the MacFarlane Trust (set up by the UK government in 1988, to provide *ex gratia* financial assistance to individuals infected with blood products contaminated with HIV) - and this would "not necessarily require the NHS to change any of its current medical policies and practices on risk arising from treatment"

12. This seems a flawed argument. The decision to compensate HIV sufferers was taken at a stage when the full implications were not apparent. In retrospect it may not have been a wise move and the Executive and UK government have consistently argued that it was a 'special case'. If Hep C sufferers are also compensated then it will be very difficult to maintain the 'special case' argument.

13. It now appears to be a fairly regular occurrence for new diseases to be identified; and for some of these diseases to have a long latency period. This has certainly been the case in

the field of blood transfusion. There is no reason to believe that further such diseases will not emerge in the future. This means that by the time that the responsible agent has identified, and preventative measures put in place, some people have suffered serious health impairment. We think it would be wrong to create an expectation that these people would automatically receive compensation for exposure to an unknown risk for which no preventative measures could be taken. We believe that adopting the Committee's first recommendation would have that effect.

14. Our proposed response to the Committee therefore rejects those recommendations that propose financial and practical support for all people who have contracted Hep C from NHSScotland blood. Instead, it offers to set up an expert group to examine the whether the general principle of offering such support is a] right, b] practicable, and if so, what universal criteria could be applied.

Adequacy of advice given to patients on risk

15. The Clinical Standards Board for Scotland does not have a remit to carry out the work proposed in this recommendation. However, applying the generic CSBS standard on patient involvement to the field of blood transfusion and blood products should have substantially the same effect.

Protocol that SE consults the committee on terms/membership of internal inquiry teams

16. This recommendation has implications which are not restricted to the Health Department. We feel the existing protocol is quite satisfactory if properly implemented.

Establish commission to examine system of negligence and fault-based compensation

17. The response to the Committee falls slightly short of their recommendation. It offers to look at the issue for all health outcomes, rather than just for blood and blood products. Also, the proposed review of the issue could conclude that the general principle was unsound or impracticable. In that case the review would not progress to the detail of when and how compensation should be awarded. Nevertheless, establishment of a review group would represent a significant gesture by the Executive.

Financial Implications

18. The Executive knows of over 530 people who have contracted Hep C from products supplied by SNBTS. Only 17 of these stand a chance of receiving out of court settlements linked to the Executive's announcement about "actions that are analogous to those dealt with in the English High Court case".

19. The remainder might well expect to benefit under the terms of the Committee's recommendation. Their financial expectation would be informed by the orders for provisional damages in the English case. In the lead cases these ranged from £10k to £210k, with an indication that claimants receiving the smaller amounts would be eligible for further payments if their illness worsened in the future.

20. In addition, tentative estimates indicate that there may be 300 bereaved families where Hep C contaminated blood could be cited as a factor in the cause of death. The

Committee's recommendation does not cover these people. However, it does cover support and assistance for families of Hep C sufferers who are still alive. The bereaved families could easily make a plausible case that they should receive some elements of the support and assistance offered to families of the living.

Establish a commission to examine system of negligence and fault-based compensation

21. Establishment of the proposed review group necessarily raises the prospect that the Executive might in theory agree to some form of ex gratia payment system in the future. The costs associated with such a system are impossible to assess without knowing the detail of what might be proposed – but might be significant.

Adequacy of advice and Protocol on terms/membership of internal inquiry teams

22. No cost implications associated with these two recommendations.

Parliament

23. The Committee has put in a request that a portion of the chamber time set aside for committee business be used to debate the report.

Presentation

24. It is inevitable that the substance of the Executive response will swiftly become available to the media. The Executive should therefore issue a press release explaining its stance. A possible basis for the component of the press release dealing with the rejection of Committee recommendation No. 1 is included as Annex C.

Consultation

25. ***[I have contacted officials in England, Wales and Northern Ireland to request comment generally – but specifically to check that they supported rejection of Recommendation 1 and were comfortable with the proposal to set up the expert group that we have proposed in part of the draft response to Recommendation 7 (by cop 20/11).***
DH has responded *"confirm that we in England support your rejection of the Committee's proposals on compensation and are comfortable with the expert group proposed in the response to their last recommendation. The latter is in line with our CMO's Advisory Group on Clinical Negligence".*
No response from Wales or NI, but NI official advised that we should consider no response as indicating that they are content. WILL DRAFT FINAL TEXT FOR THIS SECTION IMMEDIATELY PRIOR TO CIRCULATION TO CABINET – TO INCORPORATE ANY FURTHER COMMENT RECEIVED]

Recommendation

26. Cabinet is invited to endorse the attached response to the Committee report and the proposed handling strategy in para 23.

SD
Minister for Health & Community Care

22 November 2001

ANNEX A

RESPONSE TO THE HEALTH AND COMMUNITY CARE COMMITTEE'S REPORT ON HEPATITIS C IN BLOOD

RECOMMENDATIONS OF THE HEALTH & COMMUNTITY CARE COMMITTEE

1. We recommend that the Executive set up a mechanism for providing financial and other appropriate practical support to all hepatitis C sufferers who have contracted the virus as a result of blood transfusions provided by the NHS in Scotland, or which involved blood or blood products produced by the SNBTS. This support should be available to all such hepatitis C sufferers whether they are haemophiliacs or non-haemophiliacs, and it should be available regardless of whether negligence in the individual case can be proven or not. It should also be available regardless of when the individual became infected with hepatitis C, although clearly anyone who became infected after the Consumer Protection Act 1987 came into force, and who has obtained adequate damages under the Act, or who has settled adequately with the Executive's lawyers, should not also be entitled to further financial assistance.

2. We recommend that this mechanism for providing financial and other support comes into operation within a period of twelve months.

3. The level of financial assistance awarded to any claimant should be determined on the basis of need, having regard to the physical or psychological loss individually suffered, and should include redress for practical difficulties such as the inability to obtain an affordable mortgage or life assurance.

4. In determining an appropriate package of assistance, and in particular in clarifying what practical help can be offered, the Executive should consult hepatitis C sufferers – both haemophiliac and non-haemophiliac.

5. We recommend that the Clinical Standards Board for Scotland oversee an investigation into the adequacy of advice on risk offered by clinicians to individuals receiving blood transfusions or being provided with blood products. Any such investigation should consider the adequacy of advice offered not just to haemophiliacs but to non-haemophiliacs as well.

6. We recommend the adoption of a protocol between the Health and Community Care Committee and the Executive that, wherever practicable, the Executive consults with the Committee before deciding upon the terms of an internal inquiry and the membership of the inquiry team, in order to increase public confidence in the process.

7. We would also recommend that the Executive establish a commission to examine the current system of negligence and fault-based compensation and to propose alternatives. This should be with a view to promote a climate of critical self-audit by all health professionals and health managers, to reduce the level of court involvement, and to establish rapid and cost-effective support and assistance for those individuals and their families who suffer unforeseen adverse effects from health interventions.

ANNEX B

RESPONSE TO THE HEALTH AND COMMUNITY CARE COMMITTEE'S REPORT ON HEPATITIS C IN BLOOD

REPORT ON HEPATITIS C

RESPONSE FROM SCOTTISH EXECUTIVE

General points

1. The Scottish Executive values the considerable time and effort that the Committee has devoted to this issue. We welcome the report and, in particular, its conclusion that a further, independent enquiry is not desirable. We are also pleased that the Committee concluded that there was no negligence in relation to the introduction of screening or heat treatmentt and no policy to deliberately withhold information on risk from patients.

Recommendations

The Committee recommends that the Scottish Executive set up a mechanism for providing financial and other appropriate practical support to all hepatitis C sufferers who have contracted the virus as a result of blood transfusions provided by the NHS in Scotland, or which involved blood or blood products produced by the SNBTS.

2. The Executive recognises the Committee's wish to help patients who have inadvertently contracted this serious disease. We too have the greatest sympathy for those who have been infected in this way.

3. However, we cannot support the Committee's view that "providing financial support would not establish a principle that all injury caused through NHS treatment should be compensated".
[The Deputy Minister has commented that this stance needs to be complemented by "some major initiative in the core treatment of those with Hepatitis C". HP&Q has discussed this with Public Health and with Dr Keel. None of us are aware that people who have contracted Hep C from blood are experiencing any difficulty in obtaining treatment – and we would have expected to have heard if that was the case. This has not been raised as an issue by the Haemophilia Society.]
[The Committee highlights a number of forms of support that do not amount to direct compensation ie support in obtaining life insurance and mortgages and also the provision of counselling.
Mr Aldridge has commented that there might be mileage in exploring whether the Executive could speak to Financial Institutions with a view to mitigating those disadvantages. We have established that John Hutton has already written to the Association of British Insurers along these lines but they were unreceptive. The problem with mortgages appears also to be associated with the inability to get life insurance – so this seems to be a dead end.
We did originally consider whether it might be appropriate for the Executive to directly fund mortgages (on the basis that the money was eventually recoverable and thus not 'compensation'. We rejected the idea because in itself it created a difficult and far-reaching precedent – albeit on a different issue to that of compensation.

We feel that if we cannot offer either compensation or support for mortgages/insurance, then it would appear derisory to offer counselling on its own]

4. On the contrary, we believe that it is inevitable that patients who have suffered harm from other causes will feel their situation is equally deserving. They would feel that any such gesture, which did not treat them similarly, would be unfair.

5. It now appears to be a fairly regular occurrence for new diseases to be identified; and for some of these diseases to have a long latency period. This has certainly been the case in the field of blood transfusion. There is no reason to believe that further such diseases will not emerge in the future. This means that by the time that the responsible agent has been identified, and preventative measures put in place, some people have suffered serious health impairment.

6. We think it would be wrong to create an expectation in the future that these people would automatically receive compensation. It would create a precedent that would be a burden to the NHS and future administrations. It would lock up funds that could be invested in prevention strategies and treatment. In addition, it would be very likely to create a risk averse culture.

7. The Committee argues that it is simply seeking to correct an inconsistency in the operation of the "narrow" precedent created by the MacFarlane Trust. However, the decision to compensate HIV sufferers was taken at a stage when the full implications were not apparent and the Executive/UK government has always maintained that it was a 'special case'. If Hepatitis C sufferers are also compensated then it will be very difficult to maintain that 'special case'.

8. We do fully accept that the people who are harmed should be compensated if the health service is at fault - fully and quickly. The issue here is whether the NHS should also provide compassionate financial support when people are harmed through no fault of the service.

9. If there is a place for compassionate financial support in the future then we feel that it would be essential for it to be judged against agreed and published criteria. These criteria would need to be transparent, equitable and universally applicable. We shall be looking very carefully at whether such an approach is sound in principle and whether it could be made to work in practice. And we shall be doing that in close collaboration with our UK colleagues.

The Committee recommends that Clinical Standards Board for Scotland oversee an investigation into the adequacy of advice given to patients on the risk associated with receiving blood transfusions or being provided with blood products.

10. The Clinical Standards Board for Scotland does not have a remit to carry out the work proposed in this recommendation. However, there is an existing CSBS generic standard on patient focus entitled "patient involvement" which requires that patients are provided with a clear explanation of their condition and any treatment, investigation or procedure proposed, including risks and alternatives before agreeing to a course of action, to enable them to give informed consent.

11. CSBS has agreed that it would be appropriate for the accreditation process for this standard to be applied to the field of blood transfusion and blood products. Two existing

groups are well placed to provide advice to CSBS on how satisfactory performance could be assessed in this context and we will investigate the desirability and feasibility of their involvement in this way.

12. One of these is the Clinical User Group - an independent group comprised of senior clinical users of the SNBTS with donor and patient representatives. It was established by Government in 1998 and responds directly to the Minister for Health & Community Care. The other is the Coagulation Factor Working Party for Scotland and Northern Ireland. This represents the views of NHS consumers of the major blood fractionation products and could possibly be augmented with independent input if necessary.

The Committee recommends the adoption of a protocol between the Committee and the Scottish Executive that would require the Executive to consult the Committee, wherever practicable, on the terms and membership of internal inquiry teams.

13. The Executive agrees that it that it is crucially important information is properly shared with Parliamentary Committees, individual MSPs, statutory agencies, voluntary organisations and members of the public. However, a protocol already exists between Committee Clerks and the Scottish Executive setting out the arrangements for good governance and a shared understanding of how the Committees and the Executive should work together. We believe this protocol provides an adequate basis for informal consultation on a wide range of matters.

14. Nevertheless, we have pledged ourselves to be open, transparent, accessible and participative and we are fully committed to making sure the protocol is implemented in a way that achieves those ends.

The Committee recommends that the Executive establish a commission to examine the current system of negligence and fault-based compensation and to propose alternatives. This should be with a view to promote a climate of critical self-audit by all health professionals and health managers, to reduce the level of court involvement, and to establish rapid and cost-effective support and assistance for those individuals and their families who suffer unforeseen adverse effects from health interventions.

<u>Promotion of climate of critical self audit by health professionals/managers</u>

15. The Executive already has work in hand in this area aimed at providing guidance on patient safety for NHSScotland. The Clinical Effectiveness Strategy Group has set up a working group on Implementing Clinical Risk Management in NHSScotland to produce this guidance - which will be entitled "Learning from Experience." It includes links to the National Patient Safety Agency in England and emphasises the importance of using errors and near misses as a source of learning to improve the quality of care for patients.

16. The CSBS and the Performance Assessment Framework also promote self-monitoring of clinical effectiveness and aspects of safe care for patients.

<u>Reduction of the level of court involvement and establishment of a rapid, cost-effective support for individuals and their families</u>

17. The Committee states that there is currently too much onus on aggrieved patients having to prove their case in the law courts - with justice often deferred for years as cases proceed expensively through the legal system. That sentiment accords entirely with our own thinking. We feel it is important to avoid this happening wherever possible and we must strive to achieve better dispute resolution.

18. However, dispute resolution is a cross cutting issue and needs to be considered in the context of any proposed Executive civil justice strategy. The ongoing work on mediation by the Royal Society of Edinburgh is also highly relevant, as is the forthcoming Executive report on the evaluation of the NHS complaints system.

19. Nevertheless, we do feel that there is merit in setting up an expert group to explore difficulties that are specific to disputes that involve health issues. As discussed above, the remit of the group would be to examine the pros and cons of a universal system for administering financial and other support - in situations where people have been harmed but the NHS is not at fault. It would not look specifically at individual causes of harm.

> ***[Mr Robson has expressed concerns about the proposed group. He feels that there are wider implications for other organs of government and there is a risk of that pressure groups will seek to dominate its membership/findings. He wonders whether it would just prolong the issue.]***

20. We envisage that the group would have a strong independent element to its membership. There would be scope for patient input into some aspects of the group's deliberations.

21. We believe that the best time for the group to begin its work would be in the early part of next year - at which time it would have the advantage of being able to consider the outcomes of the RSE Mediation review, the Executive's report on the evaluation of the NHS complaints system, and the Review of Clinical Negligence by the Department of Health in England.

Health Planning & Quality
November 2001

ANNEX C

RESPONSE TO THE HEALTH AND COMMUNITY CARE COMMITTEE'S REPORT ON HEPATITIS C IN BLOOD

REPORT ON HEPATITIS C

BASIS FOR PRESS RELEASE CONTENT JUSTIFYING REJECTION OF EX GRATIA SUPPORT

- The Executive recognises the Committee's wish to help patients who have inadvertently contracted this serious disease. We too have the greatest sympathy for those who have been infected in this way.
- However, we do not believe the Committee is correct in its conclusion "that providing financial support would not establish a principle that all injury caused through NHS treatment should be compensated".
- The key issue here is what system the NHS should adopt for compensating people who have been harmed - not whether blood is safe.
- Blood contaminated with Hepatitis C is a thing of the past. NHSScotland is putting an unprecedented amount of resource into making sure that patients are protected from any harmful agents that may be present in blood donations. That includes taking precautionary measures aimed at agents where the risk is not even proven.
- But new agents inevitably arise and it may take many years before the risk from them becomes apparent and counter-measures can be put in place. We can never rule out the possibility of some risk to those receiving transfusions and blood products. That risk has to be balanced against the known benefits of treatment.
- How to strike the balance between the benefits of medical interventions and the risk associated with them, and how and whether people should be compensated when they are harmed as a result, are issues that affect all aspects of health service provision and concern all UK health services.
- The English High Court judgement introduced a new element into the equation. We took the view that compensation should be restricted to those cases that were strictly analogous to the judgement, but it has become apparent that the time bar provisions of the Act are more appropriate to consumer goods than to medical conditions that may take 30 years to show themselves. As a result many people are excluded.
- People affected in this way, or who are excluded because they were infected before the Act came into force, understandably feel aggrieved. The difficulty is that almost anyone can feel aggrieved when something nasty happens to them that they weren't expecting.
- We fully accept that the people who are harmed should be compensated if the health service is at fault - fully and quickly. When there is <u>no</u> fault then it becomes a question of whether or not it is right to make a compassionate gesture.
- We feel that compassionate gestures should only be made if they can be linked to a robust, logical set of criteria. People need to know where they stand - otherwise there will inevitably be some group of patients who feel they have been treated unjustly.
- We believe this issue must be considered within the wider context of a system that deals fairly and effectively with clinical negligence and no fault compensation for <u>all</u> medical conditions. The development of such a system would need to take account of conditions, maybe as yet unknown, that might arise in the future.

- What is needed are rules that can be universally applied, are transparent and equitable and which strike a fair balance. We shall be looking very carefully at whether it right to make such rules and whether it is practicable to do so. And we shall be doing that in close collaboration with our UK colleagues - because we feel the issue is so fundamental that any decision should not be made unilaterally.
- On the wider issue of the general system for compensation, Committee has also stated that there is currently too much onus on aggrieved patients having to prove their case in the law courts- with justice often deferred for years as cases proceed expensively through the legal system. That sentiment accords entirely with our own thinking. We feel it is important to avoid this happening in the future.

Health Planning & Quality
November 2001

Mr Stock

Copy to: As previous

PROPOSED RESPONSE TO THE HEALTH AND COMMUNITY CARE COMMITTEE'S REPORT ON HEPATITIS C IN BLOOD

Mr Chisholm has seen and noted your minute of 16 November. He commented that what we have not responded to is the other part of recommendation 1 about "other appropriate practical support". Mr Chisholm is of the view that this is going to be extremely difficult, not least because of the views of several Partnership MSPs. Mr Chisholm holds the view that our only hope of holding the line on financial compensation is by some major initiative in the core treatment of those with Hepatitis C.

GRO-C

John Brownlie
PS/Deputy Minister for Health and Community Care
19 November 2001