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# Stock RG (Bob)

**From:** Stock RG (Bob)
**Sent:** 30 November 2001 14:43
**To:** Minister for Health and Community Care
**Cc:** Whittle P (Pam); McCroskie J (John)
**Subject:** HepC CABINET CORRESPONDENCE

Attached - amended in the light of this morning's discussions.

I have highlighted all major changes. I have also deleted Annex C (possible basis of press release - as the emphasis is now probably inappropriate).

Bob Stock
46913

Cabinet Corresp Final.doc

Malcolm Chisholm
30 November 2001

First Minister

Copy to: Cabinet Ministers
Deputy Minister for Health & Community Care
Management Group
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 10 December. Comment should therefore be sent to the First Minister to arrive no later than close 6 December.

### 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.

15. It also offers to explore whether the Executive can help overcome the problems the patients are encountering in relation to insurance and mortgages.

### *Adequacy of advice given to patients on risk*

16. 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 but on an ongoing basis.

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

17. 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*

18. The response to the Committee offers to look at the issue for all health outcomes in the future. The offer is not retrospective. If the proposed review of the issue concluded that the general principle was unsound or impracticable, then it 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

19. 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".

20. 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.

21. 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***

22. 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***

23. No cost implications associated with these two recommendations.

### Parliament

24. 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

25. 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.

### Consultation

26. Officials in England, Wales and Northern Ireland have been asked to comment on whether their administrations support rejection of Recommendation 1 and on whether they were comfortable with the proposal to set up the expert group in response to Recommendation 7.

27. England and Wales have both expressed support. No specific response has been received from Northern Ireland but officials indicated earlier that absence of a response should be taken to indicate support.

### Recommendation

28. Cabinet is invited to endorse the attached response to the Committee report and the proposed handling strategy in para 25.

**MC**
Minister for Health & Community Care
30 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. We note that the Committee believes that it would be undesirable to establish a principle that all injury caused through NHS treatment should be compensated. We agree very strongly with that view. However, what we are unable to support is the Committee's suggestion that providing ad hoc compensation to this particular group of patients would not establish just such a principle.

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 – something that the Committee agrees is in no-one's interest.

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. We explain this further in our response to Recommendation 7.

10. Whilst we feel we have to stand firm on the general principle of compensation, we recognise the practical problems that that this patient group are facing and are keen to help if we can.

11 We note the difficulties highlighted by the Committee in relation to insurance and mortgages. We are willing therefore to explore whether there is anything the Executive could do in this area to help alleviate the problem – particularly in terms of entering into a dialogue with relevant financial institutions. To that end we would obviously welcome more information from patient groups to ensure we have the correct focus.

12 It is also an important principle of the NHS that patients receive appropriate health care and treatment for their individual needs. We will undertake a listening exercise with this group of patients to identify any specific difficulties in this area.

**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.**

13. 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.

14. 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. The application of this accreditation process will fully meet the intention behind this recommendation – but on an ongoing, rather than a one off, basis.

15. 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.

16. 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.**

17. 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.

18. 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.**

Promotion of climate of critical self audit by health professionals/managers

19. 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.

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

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

21. 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.

22. 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.

23. 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.

24. 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.

25. 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