

**Ex gratia payment scheme for patients infected with Hepatitis C as a result of
NHS treatment with blood or blood products**

Progress report following discussions with the Scottish Executive

Purpose

- To update Ministers on the development of draft proposals for a scheme of ex gratia payments for patients infected with Hepatitis C as a result of NHS treatment with blood or blood products
- to highlight areas of difficulty in setting up a scheme
- to seek Ministerial approval of the proposed direction of travel and a steer on specific aspects of the schemes development

Recommendation

You are asked to:

- note the latest position
- comment on whether you are content for the scheme to develop along the lines set out below and
- provide a steer on the issues relating to XXX

Timing

An early reply would be helpful, as the development process needs to be near completion before the schemes proposed announcement in the autumn.

Background

In January 2003 Malcolm Chisholm, the Minister for Health and Community Care in Scotland announced his intention to set-up a scheme of ex gratia payments for patients infected with Hepatitis C as a result of treatment in Scotland with NHS blood or blood products. Although within devolved competence, SofS asked that DH officials collaborate with the Scottish Executive and develop proposals for a scheme in England. Consideration would be given to the possibility of extending the scheme to all the Devolved Administrations.

The proposals below have been developed following meetings with the Scottish Executive, DH lawyers and Treasury counsel, and in discussions with the Department for Work and Pensions and HMT. The devolved administrations in Wales and Northern Ireland are not party to these developments.

Key Proposals

We propose to constitute an independent charitable Trust, with a UK wide remit, and funded jointly by the governments of England, Scotland, Wales and Northern Ireland. On submission of credible evidence, the Trust would make awards of £20,000 to those patients currently living with Hepatitis C infection as a result of NHS treatment with contaminated blood or blood products. Eligible patients would qualify for a further

payment of £25,000 should their condition deteriorate to a medically defined trigger point. The Trust would not make any other payments.

Explanation of key proposals

Scope of Scheme

DH officials and the Scottish Executive agree that a UK wide scheme is favourable to individual provincial schemes. Disparate schemes may offer inequitable awards or operate different qualifying criteria, giving rise to complaints of discrimination. A unitary, centrally managed scheme which covers the whole of the UK and bills administrations according to where the claimant lives is considered fairer, more efficient and in line with precedents. Administration costs would be shared and the scheme would operate within common parameters (as set out below).

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. Instructions have been submitted to counsel to determine whether the scheme is a devolved matter in Wales (and Northern Ireland?) and we expect advice in September. Whatever the outcome, Wales and NI need to be involved in discussions to negotiate their participation in the scheme.

Officials suggest approaching the devolved administrations once the proposed scheme has been agreed in principle by Ministers and after counsel's advice has been received. This would provide a stronger basis for discussions. If counsel advises that this issue is within devolved competence, and Wales and NI agree to the proposed scheme, we expect discussions to proceed as with Scotland. If they do not agree and wish to set up a separate scheme, the implications could be damaging if the scheme offers preferential terms, and a handling plan would be required.

If the scheme is not deemed to be a devolved matter, the options are to either devolve new powers to the Assemblies or make special provision for Wales and NI within the scope of the 'English' part of the scheme. This would mean that DH would be billed by the new Trust for payments arising from claims within Wales and NI.

Scheme Administration

Officials propose that the scheme should be administered independently and that Government should be distanced from the disbursement process. Two options were discussed as to how the scheme might develop. The first was to establish a scheme under the umbrella of the Macfarlane Trust, a UK arms-length body that makes ex gratia payments to 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.

The former option is preferred because the Macfarlane Trust provides a ready built administrative infrastructure and it already administers the smaller Eileen Trust (which provides payments to non-haemophiliacs who have contracted HIV via NHS blood and

blood products). According to independent reviews commissioned by DH, both Trusts are well managed. It is thought that the Macfarlane Trust would be amenable to this proposal, providing adequate administrative funding is made available, but it is impossible to approach them at this stage.

The alternative - setting up a new Trust from scratch - would take far longer to establish, would cost more to start up and administer, and would not benefit from the management expertise at the Macfarlane and Eileen Trust. However, should the Macfarlane Trust not wish to be involved in the proposed scheme, this would be the preferred option.

Parameters of proposed scheme

Draft Eligibility criteria

1. In order to qualify for payment, all claimants will be required to provide evidence in their application that they were infected, or on the balance of probabilities were most likely infected, with Hepatitis C as a result of treatment with contaminated blood/blood products supplied by the NHS before the introduction of heat treatment (month 19XX) and donor screening (Sept 1991). [Infected intimates?]
2. Subject to satisfying paragraph 1 above, those qualifying for the initial payment of £20,000 shall be:
 - 2.1 Persons diagnosed and living with Hepatitis C
 - 2.2 Persons whose therapeutic treatment enabled them to clear the virus
3. Subject to satisfying both paragraphs 1 and 2.1 above, those qualifying for the further payment of £25,000 shall be:
 - 3.1 Persons whose condition has been confirmed by a medical practitioner to have advanced to [a medically defined trigger point]
 - 3.2 Persons co-infected with HIV who are in receipt of payments from the Macfarlane Trusts, Eileen Trust or any other government sponsored special payments trust and whose condition has been confirmed by a medical practitioner to have advanced to [a medically defined trigger point]
 - 3.3 All persons who receive a liver transplant

Applicants not qualifying for payments:

- Persons co-infected with HIV who are in receipt of payments from the Macfarlane Trusts, Eileen Trust or any other government sponsored special payments trust and whose condition has not advanced to the medically defined trigger point, will not qualify for the initial payment
- Persons who spontaneously cleared the virus after infection (ie, those who suffered from acute Hepatitis C infection)
- Persons adjudged by the Trust to have been infected with Hepatitis C as a result of infection arising from any other circumstances than that listed above
- Relatives, dependants, personal representatives and/or the estates of deceased persons claiming on their behalf

Variations:

- Persons 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.
- Persons 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.

Liability:

- Persons 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.

Issues under discussion

Supporting evidence

The level of evidence required to support an application would be based on the eligibility criteria. This might include the submission of medical records, blood samples, statements from clinicians, blood batch numbers and details of any treatment received. [Infected intimates?] Where there is clear evidence of entitlement, applications would be nominally approved by the Secretary of State (following advice from the Trust, whose Executive would authorise payment). Where irrefutable evidence is not available (lost medical records, retirement of clinicians etc) the Trust would consider applications on the balance of probabilities.

The Macfarlane and Eileen Trusts appoint a panel of experts and lay people to make judgements in these circumstances. A similar panel is envisaged for the new Trust, and as well as ruling on marginal cases, it would also review appeals from applicants dissatisfied with the Secretary of State's decision. The Secretary of State would be bound by the decisions of the panel. [All applications from infected intimates are referred to the panel?]

Medical trigger point

[Reasons for definition chosen and how arrived at]

Processing applications

[See flow diagram]

Potential areas of contention/non-qualifying patients

(No payments to family/representatives/estates etc)

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.

Financial implications

Summary of recommendations

Next steps (work in hand)

Conclusion

(Seeking approval of direction of travel and, if granted, preliminary proposals set out in this paper)

(Also, steer from Minister re. when to involve Wales and NI)