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CONTAMINATION OF BLOOD AND BLOOD PRODUCTS WITH HEPATITIS C AND HIV – PUBLIC INQUIRY IN SCOTLAND

Summary

1. This is to advise you about the announcement on 23 April of a public inquiry in Scotland. We recommend that you maintain the position that an inquiry in England is unnecessary.

2. Legal opinion from SOL is supportive of this position and is attached at Annex A. A short note summarising the background to this issue is at Annex B.

Scottish inquiry

3. The Scottish National Party made a commitment in February 2007, prior to the last election to the Scottish parliament, to convene a public inquiry into contamination of NHS blood and blood products. The Scottish health minister confirmed in August that an inquiry would be set up in Scotland, once Lord Archer's independent inquiry had concluded. The inquiry is likely to focus on the period up to 1991, when screening of blood donations for hepatitis C was introduced.

4. This situation changed in February this year when a judicial review in Scotland concluded that both the Lord Advocate and the Scottish Government (SG) had acted unlawfully in refusing to convene Fatal Accident Inquiries or public inquiries into two deaths from contamination by hepatitis C, on the basis that the refusal was

incompatible with Article 2 of the European Convention on Human Rights. (There is no inquest system in Scotland – a Fatal Accident Inquiry is broadly equivalent.) The SG decided not to appeal and is now required to return shortly to the judge to say what action it will take in light of the ruling.

5. At a meeting with SG officials and lawyers on 14 March, DH officials were advised that an inquiry will be announced in the Scottish Parliament on 23 April. The SG estimates the cost of the inquiry at £1mn in 2008/09 and £2mn in 2009/10. It is expected that the chair will be appointed by the SG shortly.

6. The inquiry will cover contamination from both hepatitis C and HIV, although consultation with interested parties on the scope is still to be completed. The inquiry will be a statutory one i.e. it will be held under the Inquiries Act 2005. Under the 2005 Act, an inquiry in Scotland must be confined to Scottish matters. However, the findings and recommendations are highly likely to be seen by campaigners as relevant to the rest of the UK.

7. Legal advice is at Annex A. Briefly, there is no legal reason for Ministers to extend the remit to England, but we could co-operate with a Scottish inquiry if so minded.

8. We have received no formal invitation to join the inquiry and the SG is not expecting that we will do so, unless substantial new evidence emerges that changes the situation. We have indicated that we will, as with the Archer inquiry, aim to be helpful by supplying documentary evidence where we can do so.

Pros and Cons for the UK Government of joining the Scottish public inquiry

9. You have indicated previously that DH officials should not make any commitment that England may join the Scottish inquiry (i.e., make it a joint inquiry with scope to consider England, and possibly Wales). I set out below the advantages and disadvantages of doing so.

- Advantages of joining the Scottish inquiry

- The UK Government could have some influence over the proceedings, in particular the scope and identity of the inquiry panel (the Scottish government proposes that this will consist of a Chairman who will be a judge).
- Initial reaction from stakeholders and the media would be likely to be favourable, although such a change of direction would inevitably attract comment.

- Disadvantages of joining Scottish inquiry

- Public inquiries are very costly and the costs are not easy to control.
- The UK Government would have little influence over the direction of proceedings once the inquiry was established.
- UK Government Ministers, officials and NHS bodies from England may be summoned to give evidence.
- The recommendations would apply to the UK.
- There would be a diversion of funds which would be better spent on healthcare given the minimal chance of adding to current knowledge or learning of new lessons.

- Advantages of staying out of Scottish inquiry

- UK Government Ministers, officials and NHS bodies from England and Wales cannot be summoned to give evidence (but could choose to do so voluntarily).
- The recommendations would not apply to the UK, and although they might be seen as relevant, the UK would have options as regards its policy in response to the inquiry.
- Cost savings: a Scottish commitment is met from Scottish Government funds.

- Disadvantages of staying out of Scottish inquiry

- It may exacerbate Scottish-UK Government relations.
- There may be a legal challenge to this decision, citing Article 2 of ECHR, as in Scotland (although lawyers believe there are good reasons why this would be unlikely to succeed in England, as set out in Annex A).
- There is likely to be strong criticism from campaigners, interested Parliamentarians and media, requiring strong defence of the UK position.

Summary and Recommendation

10. This is a Scottish inquiry in response to:

- A policy decision of the Scottish Government, as set out in their manifesto.
- A legal decision applying to Scotland (which the Scottish Government has chosen not to contest).

11. There is no clear legal requirement on the UK Government to hold a similar inquiry (by joining the inquiry or otherwise) and thereby extend the scope to England.

12. The very limited advantage of joining does not justify the considerable disadvantages, including:

- Loss of control on whether and how to give evidence.
- Fewer option in terms of policy on final recommendations.
- Cost.

13. We continue to have grounds for maintaining that an inquiry covering England is unnecessary, although we understand the different position in Scotland.

14. We **recommend** that the DH response to the Scottish inquiry is:

- To say that we understand the legal need for an inquiry in Scotland but emphasise that this does not apply to England (for the reasons set out in Annex A).
- To leave the Scottish Government to set up an inquiry limited to devolved issues.
- Be as helpful as possible with any official documents we may have and which have not already been published.
- Keep to the strong line justifying the UK Government position in relation to an inquiry, namely:
    - There is no new evidence showing any lack of good faith in policy or treatment.
    - All relevant official documents are now in the public domain.
    - There have been previous court cases and settlements, and three funds set up to make payments to those affected (Annex C gives details).
    - There is no prospect of adding to current knowledge about how infections occurred and any lessons to be learnt have been learnt.
- We must be careful to avoid any impression that the UK Government has decided in advance there will be no response whatever the inquiry concludes. However, this will enable freedom of action over policy, including freedom to respond when the inquiry reports.

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Annexes (attached)

A. Legal opinion from SOL
B. Background note
C. Funds providing payments to those affected

Annex A. Summary of legal opinion from SOL

A1. Legal advice on the implications for the UK Government of the Scottish judicial review supports the view that there is no similar obligation to hold an inquiry covering England. This is because:

a. Article 2 of the European Convention on Human Rights imposes a duty to carry out an effective investigation if there has been a possible breach of the duty to protect life and/or where state agents are responsible. When a person dies following treatment in hospital Article 2 also requires a system capable of providing a practical and effective investigation of the facts and the determination of any civil liability.

b. The duty to carry out an effective investigation under Article 2 of the ECHR may be met by a combination of processes such as civil, criminal and disciplinary proceedings along with an inquest.

c. There is no inquest system in Scotland, and neither a Fatal Accident Inquiry nor a public inquiry had been set up into these two deaths. Nor would civil proceedings be likely to offer an effective investigation.

d. In England there is the possibility of an inquest.

e. Further, there has already been substantial investigation into hepatitis C infections such as reports on the self-sufficiency of blood products and on the documents relating to the safety of blood products.

f. The relevant facts and documents are in the public domain.

g. A full public inquiry would not add to current knowledge about how infections happened or the steps needed to deal with this kind of problem now or in the future.

h. There is little risk of future infection of hepatitis C from blood or blood products and that has been the case since 1985.

i. All the important lessons have been learnt and there are no new issues or areas for improvement which remain to be identified.

j. Thus there would be no practical benefit to be gained from a full public inquiry which would be a time consuming and expensive process, diverting funds away from health services and would depend on the recollection of witnesses about events which took place over 20 years ago.

k. There is an additional argument in the case of hepatitis C through blood transfusions (as opposed to from Factor 8 for

haemophiliacs) in that this issue was considered in a class action under the Consumer Protection Act 1987 in the case of *A and another v National Blood Authority and another* (2001). This considered whether Hep C infections through blood transfusions could have been avoided. Therefore it is arguable that there has already been an effective investigation into this particular issue.

l. The objectives of Article 2 investigations, namely minimising the risk of future deaths, giving the beginnings of justice to the bereaved and assuaging the anxieties of the public have already been served.

m. Similar grounds apply to contamination with HIV. The causes are well known and are set out in the relevant medical and scientific literature. Measures have been in place since 1985 to prevent further risk. There is no case that, after this time, an inquiry is necessary to establish the facts and prevent further cases.

A2. As the Scottish inquiry must be confined to Scottish matters, it cannot summon UK Government Ministers or anyone speaking on behalf of the UK Government, which would include officials of DH, NHS Blood and Transplant (NHSBT), and any other NHS body performing delegated functions on behalf of the Secretary of State. It would be a matter of policy decision whether anyone should attend or give evidence on behalf of the UK Government.

A3. However, the UK Government could alternately decide to cooperate or participate in the inquiry informally if it were minded to do so.

Annex B. Background

B1. Most patients with haemophilia who were treated with blood products (clotting factors) in the 1970s through to the mid-1980s were infected with hepatitis C virus (originally known as Non-A, Non-B hepatitis (NANBH)) and many with HIV/AIDS virus. All patients receiving blood transfusions were also at some risk of infection with hepatitis C until 1991.

B2. It was not possible to produce effective clotting factors for the treatment of haemophilia that were free from risk of HIV and NANBH until 1985 when heat-treatment was introduced. The hepatitis C virus was not identified until 1989, and the screening of donor blood was introduced in September 1991.

B3. There are a number of haemophilia lobby groups who believe that there should be a public inquiry into the issue of the contamination of NHS blood and blood products with hepatitis C and HIV. Following the Scottish judgment it is likely there will be further calls for a public inquiry in England. This is linked to the issue of compensation, as campaigners may believe there is new evidence to emerge that could support their case for compensation.

B4. This and previous administrations have maintained that an official inquiry is unnecessary and not justified, given:

- the time that has elapsed
- previous litigations and settlements (funds have been established to make payments to those infected with HIV and hepatitis C – see Annex C)
- the fact that we have carried out a full review of all the papers and found no evidence whatsoever of any wrongdoing at the time by government or the NHS
- the lack of prospect of any new lessons being learnt
- and the high cost of a public inquiry (eg. Bristol Royal Infirmary, over £14 million; Royal Liverpool Children's (Alder Hey) inquiry, £3.5 million; Victoria Climbié inquiry, £3.8 million)

B5. The Department's position that an inquiry is not necessary was not helped by the loss or destruction of some papers covering the period in question, about which we have been quite open. In May 2007 we published a review of documentation on blood safety, 1970-1985 (Non A Non B hepatitis), together with relevant documents, including an internal DH audit from 2000 into the loss of some documents.

B6. Lord Archer of Sandwell set up an independent inquiry into contaminated NHS blood and blood products and its consequences for the haemophilia community and others in 2007. It is expected to report in the spring.

B7. We have cooperated with Lord Archer by meeting with the inquiry team and providing a copy of the report "Review of Documentation Relating to the Safety of Blood Products 1970-1985". We have also provided to the inquiry and released into the public domain a large number (around 18,000 pages) of official documents on blood safety issues from 1970-1986. These are available for scrutiny on the Department's website and at the Parliamentary libraries. We also provided to the inquiry some additional information regarding the chronology of certain events.

Annex C. Funds providing *ex gratia* payments to those infected with HIV or hepatitis C through NHS treatment

	Macfarlane Trust	Eileen Trust	Skipton Fund
When established	March 1988	1993	January 2004
Who benefits	Haemophilia patients who contracted HIV following treatment with NHS blood products prior to October 1985 (when screening of donations for HIV was introduced); families of deceased infected patients; partners infected by haemophilia patients infected by NHS blood products.	People (other than haemophiliacs) who have contracted HIV through NHS treatment with infected blood products. This may include dependents and widows.	Patients infected with hepatitis C through NHS contaminated blood and blood products before September 1991 (when screening of donations for hep C was introduced)
Type of payments	Includes regular monthly payments, seasonal payments and one-off grants. (Monthly payments vary from around £1000 to around £6000 pa depending on circumstances.)	May include regular monthly payments, winter payments and one-off grants. (Monthly payments average £4000 pa.)	People infected with hepatitis C receive lump sum payment of £20,000 (Stage 1 payment). Those developing more advanced stages of the illness, such as cirrhosis or liver cancer, get a further £25,000 (Stage 2 payment).
Number of patients (and/or their dependants) to whom payments were made up to 31 March 2007	The number of registrants peaked at 970 in 1991. In 2007 there were 366 registrants, 42 partners who had been infected and 170 widows and dependent children.	27 people in 2006/07.	4,295 patients (appeals against some non-payment decisions are being processed)
Amount of funding in 2006-07	£3.7 million	£177k	£7 million
Total cost of funding to 31 March 2007	£42 million (main Macfarlane Trust only – does not include Macfarlane special payments 1 and 2 – early 1990s)	£1.2 million (estimate)	£88.8 million