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The Scottish Government

The Rt Hon Lord Penrose

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Dear Lord Penrose

The purpose of this letter is to provide further explanation of certain aspects of the terms of reference (enclosed) for the Inquiry.

The inquiry being established under the 2005 Act will be a public inquiry (see section 18), chaired by a senior independent judge (see sections 8 & 9), under the provisions of the 2005 Act. The 2005 Act empowers, and places obligations on, various persons, who now require to perform their respective statutory roles. The Scottish Ministers have settled the terms of reference of the inquiry, following consultation with the Chair: section 5. The Scottish Ministers have power to make a determination under section 40(4) concerning awards to be made by the Chair in respect of expenses. Both the Scottish Ministers and the Chair have power to place restrictions on evidence and on attendance at the inquiry: see section 19.

Like the Scottish Ministers, the Chair too has statutory powers and duties under the 2005 Act, which he or she will be left to perform. The Chair will be aware decisions once taken may in appropriate circumstances be subject to judicial review. These include the power to decide on procedure and conduct of the inquiry (section 17), to require production of evidence (section 21), to make awards of expenses (section 40) and to apply the Inquiries (Scotland) Rules 2007. As a public authority, the Chair will require to take account of the Convention rights of all those involved in the inquiry process.

In relation to the provision of relevant material and evidence the matter is governed by the Act and the Inquiries Rules, for example, rules which provide for the recovery of and access to relevant material: see rules 8, 9 & 11, and section 21 of the 2005 Act. The Chair's powers under section 21 may be restricted in cases of e.g. confidentiality or public interest immunity; and there are limits to the Chair's powers to require evidence in Scottish inquiries (section 28) or where there is a risk of damage to the economy (section 23).

The earliest reference in the scientific literature, identified in the Report of the Lindsay Tribunal, to the development of liver disease in haemophiliacs associated with the use of blood factor products is in 1974. The investigations of the Inquiry should therefore focus on the period beginning 1 January 1974.

The Inquiry should look at specific issues arising prior to 1974 only if there is robust evidence available as a basis for investigation, and it can be demonstrated that this is of significant relevance to meeting the terms of reference of the Inquiry.

The hepatitis C virus was first isolated and fully identified in 1989. As noted above, knowledge about the virus had been developing since the mid 1970s when the scientific community began to comment on asymptomatic liver disease in haemophiliacs treated with blood products. Although the disease could be classified as hepatitis, being an inflammation of the liver, it was not identifiably the result of either the hepatitis A or the hepatitis B virus. The condition became known as Non-A Non-B hepatitis until the isolation of the virus in 1989. References to hepatitis C in the terms of reference are to be understood as relating to Non-A Non-B hepatitis prior to 1989.

Knowledge and understanding hepatitis C, and the scientific and clinical evidence, developed and evolved through the 1970s and 1980s. Initially hepatitis C was regarded as a relatively mild condition. Through the 1980s there was an emerging international consensus that it could lead to serious liver damage, including cirrhosis and cancer of the liver. The Inquiry should examine the development of international evidence on and understanding of hepatitis C, drawing as necessary on primary clinical and scientific sources, peer-reviewed literature, and secondary international analysis of these sources.

Guidelines and standards for the four UK blood services are generally agreed at a UK level, on the basis of scientific advice and with the approval of ministers where necessary. Prior to devolution in 1999, decisions relating to Scotland were taken by Scottish Office Ministers within the framework of collective responsibility for government decision-making. The Inquiry will be expected to consider where necessary how such decisions were taken, and how these related to scientific advice and decisions of the UK government.

The Inquiry may also require to consider the implications for patients treated by the NHS in Scotland of the role of the UK government in the regulation and licensing of blood products under the Medicines Act 1968.

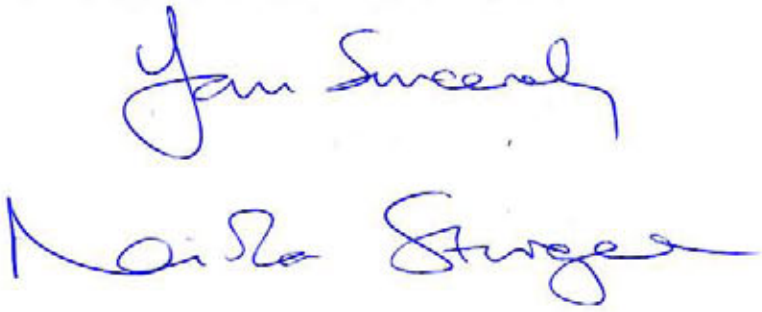
A significant volume of papers relating to the role of the UK government have been published, and are available at the Department of Health website:

http://www.dh.gov.uk/en/index.htm;
http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_076693;
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4130917

The Department of Health have also indicated that they will provide all reasonable and appropriate assistance in supplying information to the Inquiry, similar to that provided to the Lord Archer Inquiry – the Independent Inquiry into Contaminated Blood and Blood Products – http://www.archercbbp.com/

The terms of reference require the Inquiry to investigate the deaths of Reverend David Black and Mrs Eileen O'Hara, with particular reference to the circumstances in which they became infected with the hepatitis C virus, HIV or both. The Lord Advocate will consider whether there are other similar deaths. Where appropriate, Ministers will refer such deaths to the Inquiry.

This will be done through amendment to the terms of reference and in consultation with the Chair.



NICOLA STURGEON

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Enclosure 1

Hepatitis C/ HIV Inquiry Terms of Reference

Term of Reference 1:

To investigate the systems in place in Scotland for the collection, treatment, licensing, testing, preparation for supply and supply for use by the NHS of blood and blood products with particular reference to the risks of transmission of the hepatitis C virus and HIV to patients treated by the NHS in Scotland, including the role of government in regulation and setting guidelines and standards.

Term of Reference 2:

To investigate the systems in place for informing patients treated by the NHS in Scotland of the risks associated with the use in their treatment of blood or blood products, with particular reference to the risks of infection with the hepatitis C virus and HIV.

Term of Reference 3:

To investigate the systems in place in Scotland for obtaining consent from, and testing for infection with hepatitis C and HIV, patients treated with blood or blood products, and informing any patients found to be so infected.

Term of Reference 4:

To investigate the systems for recording and monitoring the numbers of NHS patients in Scotland treated with blood and blood products, with particular reference to the numbers exposed to risk of infection with the hepatitis C virus and HIV and the numbers contracting either or both such infections as a consequence of such treatment.

Term of Reference 5:

To examine the circumstances generally in which patients treated by the NHS in Scotland became infected with hepatitis C, HIV, or both through the use of blood or blood products in the course of their treatment, taking account of the development of scientific and clinical understanding and evidence internationally.

Term of Reference 6:

To investigate the deaths of Reverend David Black and Mrs Eileen O'Hara, with particular reference to the circumstances in which they became infected with the hepatitis C virus, HIV or both.

Term of Reference 7:

To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland, including NHS Boards and the Scottish National Blood Transfusion Service ("SNBTS"), their officers and employees and associated agencies, once hepatitis C and HIV were identified, to trace individuals who might have become infected with one or both of them as a result of receiving blood or blood products; and to identify any other or further steps that might reasonably have been taken to trace such individuals.

Term of Reference 8:

To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland including NHS Boards and SNBTS, their officers and employees and associated agencies, to prevent the provision of infected blood and blood products.

Term of Reference 9:

To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland including NHS Boards and the SNBTS, their officers, employees and associated agencies to inform individuals who might have received infected blood or blood products of the risks associated with their treatment for themselves and their families; and to offer treatment to any individual at risk, and to identify any other or further steps that might reasonably have been taken to inform and to treat such individuals.

Term of Reference 10:

To examine any particular adverse consequences for patients treated by the NHS in Scotland and their families of infection through blood and blood products with hepatitis C and HIV, including the treatment offered.

Term of Reference 11:

To identify any lessons and implications for the future, and make recommendations.

Term of Reference 12:

To report as soon as practicable.