1. Liz Woodeson (agreed)

2. MS(PH) From: William G Connon

Date: December 2007

Copy: As attached

Appointment of a Chairman and Members to the Advisory Committee on the Safety of Blood, Tissues and Organs

Issue

 To note the appointment of the Chair and Members of the new UK wide committee to provide advice on the safety on blood tissues and organs has been completed. The appointments were carried out by the Appointments Commission. See **Annex A** for membership.

Recommendation

2. For information.

Timing

3. Not Urgent. A press release will be issued on XXX and a copy of the press release is at **Annex B**.

Background

- 4. An external independent review of the advisory committee on the Microbiological Safety of Blood Tissues and Organs for transplantation (MSBTO), commissioned at the end of 2006, recommended that a new independent scientific committee to advise on all risks associated with the collection and use of blood, tissues and organs be established.
- 5. It was recommended that the new committee be more visibly independent, with the appointment of an independent Chair and new membership to reflect the expertise needed. There was also a need to revise the terms of reference of the new committee.
- 6. The submission to MS/PH on 21st June 2007 gives full details and is attached at **Annex C**.

Financial Implications

7. None. It will be funded from the Health Protection Infectious Disease and Blood Policy administrative budget.

Communications and Stakeholder Engagement

8. The Scottish, Welsh and Northern Irish government officials have been fully involved in the establishment of the committee, as have the UK Blood and Transplant Services.

Conclusion

9. We recommend that you note the Appointments Commission Board's recommendations on the membership of the new Advisory Committee on the Safety of Blood, Tissues and Organs.

William G Connon Head of Blood Policy

Copied to:

Rob Parsons Jude Atkin David Harper Elizabeth Woodeson Lindsey Davies Ailsa Wight Janet Gibson Gareth Jones Triona Norman Rowena Jecock Peter Bennett Zubeda Seedat Rebecca Cardigan Aileen Keel Svlvia Shearer Elizabeth Mitchell Cathy White

Annex A: Membership of the Advisory Committee on the Safety of Blood, Tissues and Organs

The membership of the of the new committee is given below. However, the important post of a health economist was not filled during the initial recruitment exercise and the Appointments Commission has re-advertised this post so that the committee is properly constituted to fulfil its remit when it holds its inaugural meeting on 23rd January 2008.

CHAIRMAN

Professor John Forsythe has been appointed as Chair of the new committee. He is a consultant Transplant Surgeon at the Royal Infirmary of Edinburgh and has been vice-president and secretary of the British Transplantation Society. He is also a Clinical Director of Transplant/GI/Renal Services at the Royal Infirmary of Edinburgh and is a Reader at the University of Edinburgh. He is Specialty Advisor to the Chief Medical Officer of Scotland, Chairman of the Scottish Transplant Group (Advisory Group to the Scottish Minister of Health), and a Non-executive Board Member for NHS Quality Improvement Scotland.

Blood/Transplant Service Manager

Dr George Galea, has been a National Tissue Services Director in Edinburgh since 1999. Between 1993 and 1999 he was the Regional Transfusion Director in Inverness and Dundee and between 1989 and 1993 he was a Consultant in Transfusion Medicine. Dr Galea is Chair of the UK NIBSC/BTS Standing Advisory Committee on Tissues and Stem Cells and Chair of MSBTO Bone and Tissues sub group. He is also Member of the Scottish National Blood Transfusion Service and Member of the UK/BTS Standing Advisory Committee on Donor Care and Selection.

CJD Expert

Dr Hester Ward, is a Consultant in Public Health and Epidemiology, since 2005 she became Deputy Director of the National CJD Surveillance Unit in Edinburgh. Dr Ward is Member of the National CJD Incidents Panel, the Specialist Advisory Committee of Transfusion Transmissible Infections Working Group on CJD and the Lothian Research Ethics Committee.

Epidemiology/Public Health

Dr Harpreet Kohli, has been Medical Advisor with the NHS Quality Improvement Scotland since 2003, prior to this he was Medical Director at the Health Technology Board for Scotland. He is also an Honorary Clinical Senior Lecturer at the University of Glasgow. Between 1990 and 2001 Dr Kohli worked as a Consultant in Public Health Medicine and Lecturer in Public Health Medicine.

<u>Haematologist</u>

Dr Michael Potter, is a Consultant Haematologist and Director of Bone Marrow Transplantation at the Royal Marsden NHS Foundation Trust. He is a JACIE inspector (European accreditation scheme for Stem Cell transplant Centres), an Examiner for the Royal College of Pathologists and Member of the UK Childrens Cancer Study Group.

Professor Marc Turner, is a Professor of Cellular Therapy, University of Edinburgh and Associate Director, Scottish Centre for Regenerative Medicine. He is also a Consultant Haematologist with the Scottish National Blood Transfusion Service and NHS Lothian and Clinical Director of the Edinburgh Blood Transfusion Centre and Aberdeen Blood Transfusion Centre, as well as, Lead Clinical Director of the Scottish National Blood Transfusion Service.

Immunologist

Dr Anthony Warrens, is a Reader and Honorary Consultant Physician in the Department of Immunology and Renal Unit of the Imperial College London and the Director of Clinical Immunology Service at the Hammersmith Hospital. He is Elected Treasurer and Trustee of the British Transplantation Society, Elected President and Council Member of the Royal Society of Medicine (Section of Transplantation and Section of Nephrology).

IVF/Fertility/Stem Cell Specialist

Professor Peter Braude, is Head of Department of Women's Health, School of Medicine, and Division of Reproduction and Endocrinology, School of Biomedical and Health Sciences at King's College London. He is also Professor of Obstetrics and Gynaecology and Hon Consultant in Reproductive Medicine at Guy's and St Thomas' Foundation Trust.

Medical Director from Blood Services

Professor Ian Franklin, is Professor of Transfusion Medicine at the University of Glasgow, Honorary Consultant of the Bone Marrow Transplant Unit at the Royal Infirmary and National Medical and Scientific Director for the Scottish National Blood Transfusion Service. He is also a European Blood Alliance Board Member and Member of the UK Medical Research Council Data Monitoring & Ethics Committee.

Microbiologist/Bacteriologist/Virologist

Dr Eithne MacMahon, is a Consultant Virologist at Guy's and St Thomas' NHS Foundation Trust, an Honorary Senior Lecturer at the Department of Infectious Diseases at King's College London School of Medicine at Guy's, King's College and St. Thomas' Hospitals, and a recognised Teacher at the University of London.

Professor Richard Tedder, is Professor of Medical Virology at the University College London, Consultant Virologist to the National Blood Service and Head of the Blood Borne Virus Unit and The Centre for Infections at Colindale. He is Member of the Medical Research Council, the Advisory Group on Hepatitis and the Health Protection Agency.

Dr Tyrone Pitt, is Deputy Director and Head of the Laboratory of HealthCare Associated Infection, prior to this he worked as a TopGrade Microbiologist and a Principal Microbiologist. He is an Honorary Senior Lecturer at the National Heart and Lung Institute, University of London and London School of Hygiene and Tropical Medicine. Dr Pitt is also a Consultant Bacteriologist to the National Blood Services Microbiology Laboratory and Microbiologist Advisor to the UK Stem Cell bank.

NHS Management

Professor Joanne Martin, is Professor of Neuropathology, Consultant Histopathologist and Clinical Director of Diagnostics and Therapeutics at the Barts & The London School of Medicine & Dentistry. She is also Member of the Research Advisory Panel of the Motor Neuron Disease Association, a Keele Benchmarking Representative for the Royal College of Pathologists and a Pathological Society of Great Britain and Ireland Committee Member.

Nurse

Mrs Catherine Howell, is a Transfusion Liaison Nurse Manager for NHS Blood and Transplant, responsible for the NHSBT "Better Blood Transfusion" programme. Prior to this she was the National Lead Nurse (Clinical Development) for the National Blood Service.

Orthopaedic Surgeon

Professor Hamish Simpson, is Professor of Orthopaedics & Trauma for the Department of Orthopaedic Surgery at the University of Edinburgh. He is also the Chair of Scottish Committee for Orthopaedics and Trauma Transitional Board for Surgery for Scotland.

Patient Representative

Mr GRO-A is a Senior Development Manager for South East England Development Agency, responsible for over £300m private investment at Chatham Maritime. Prior to this he was Founder and Managing Director of a development company, Connaught Commercial Group. He is member of the Rochester Riverside Project Board, the Chatham World Heritage Site Steering Group and Chatham Vision Advisory Group.

Physician

Professor Deirdre Kelly, is Professor of Paediatric Hepatology at the University of Birmingham, Consultant Peadiatric Hepatologist and Director of

the Liver Unit for Birmingham Children's Hospital NHS Trust and Medical Director of Medical Research Education and Research. She is also Chair of the National Advisory Committee for Enquiries into Child Health, Member of the Advisory Committee on Clinical Excellence Awards and Commissioner on the Healthcare Commission.

Risk Assessment Manager/Communicator

Dr Keshwar Baboolal, is a Consultant Nephrologist, Transplant Physician and General Physician at the University Hospital of Wales. He has acted as Adviser to the Scottish Parliament and is LLM and MBA qualified. Dr Baboolal has developed specialist knowledge in the use of probability analysis to measure variability and uncertainty and has a particular interest in healthcare finances and financial risk.

Solid Organ Transplant Surgeon

Professor John Dark, is a Professor of Cardiothoracic Surgery, Consultant Cardiothoracic Surgeon and Director of Cardio-Pulmonary Transplantation at the Freeman Hospital. He is a member of the Ethics Committee, the British Transplantation Society and Founder Member of the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA).

Annex B Press Release

New Chair and members of the Advisory Committee on the Safety of Blood Tissues and Organs (ACSBTO) announced

The Department of Health today [date] announced the appointment of a Chair and 18 Members to the Advisory Committee on the Safety of Blood Tissues and Organs.

This announcement is made on behalf of all the UK Health Ministers.

The Advisory Committee on the Safety of Blood Tissues and Organs has been independently established by the Appointments Commission, as an Advisory Non-Departmental Public Body in accordance with the Office of the Commissioner for Public Appointments Code of Practice. This UK-wide Committee will provide the Ministers with independent expert advice on issues of safety relating to blood, tissues, cells and organs. In addition, it will also provide advice to the UK blood and transplant services.

The Appointments Commission on behalf of UK Ministers appointed Mr John Forsythe, a highly respected consultant Transplant Surgeon at the Royal Infirmary of Edinburgh, as Chair of the new Committee on 30th October 2007. The appointments of Members of the Committee will be made effective from 1st December 2007 for a period of up to four years. These posts are not remunerated.

Mr Forsythe said "I welcome this opportunity to work with so many eminent colleagues in order to secure the best scientific technical and operational advice on the safety of blood, tissues and organs. The independent advice which we give will enable departments, blood services and transplant professionals to manage the risks in this important area and continue to provide a first class service to the NHS and the public. Communicating our findings to the public, to donors and to health professionals, throughout the UK, will be one of our key priorities."

All appointments are made on merit and political activity plays no part in the selection process. However, in accordance with the original Nolan recommendations, there is a requirement for appointees' political activity (if any declared) to be made public. None have been declared.

The Committee will hold its inaugural meeting on the 23rd January 2008.

The post of a health economist has been readvertised and we aim to have an appointee in time of the first meeting. The structure of the Committee is as follows:

CHAIRMAN

Mr John Forsythe has been appointed as Chair of the new committee. He is a consultant Transplant Surgeon at the Royal Infirmary of Edinburgh and has been president and secretary of the British Transplantation Society. He is also a Clinical Director of Transplant/GI/Renal Services at the Royal Infirmary of Edinburgh and is a Reader at the University of Edinburgh. He is Specialty Advisor to the Chief Medical Officer of Scotland, Chairman of the Scottish Transplant Group (Advisory Group to the Scottish Minister of Health), and a Non-executive Board Member for both NHS Quality Improvement Scotland and NHS Blood and Transplant.

Blood/Transplant Service Manager

Dr George Galea, has been a National Tissue Services Director in Edinburgh since 1999. Between 1993 and 1999 he was the Regional Transfusion Director in Inverness and Dundee and between 1989 and 1993 he was a Consultant in Transfusion Medicine. Dr Galea is Chair of the UK NIBSC/BTS Standing Advisory Committee on Tissues and Stem Cells and Chair of MSBTO Bone and Tissues sub group. He is also Member of the Scottish National Blood Transfusion Service and Member of the UK/BTS Standing Advisory Committee on Donor Care and Selection.

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Head of the Blood Borne Virus Unit and The Centre for Infections at Colindale. He is Member of the Medical Research Council, the Advisory Group on Hepatitis and the Health Protection Agency.

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Annex C Press Release Submission to MS(PH) on 21 June 2007 to formally establish the new committee as an independent ANDPB

Jacky Buchan PS/ MS (PH) Louise Gillespie PS/ MS (HS) From: William G Connon

Date: 21 June 2007

Copy: As attached

Proposed Establishment of a New Independent Advisory Committee on the Safety of Blood, Tissues and Organs

Issue

10. To seek your agreement to replace the existing committee on the Microbiological Safety of Blood, Tissues and Organs for transplantation (MSBTO) with a formally constituted expert advisory committee.

Recommendation

- 11. You are asked to agree that we replace the existing committee with a new Advisory Non-Departmental Public Body (ANDPB). The safety of blood, tissues and organs is a key policy area and it is vital DH secures the best scientific, technical and operational advice on the assessment and management of risk in this area in a transparent and independent way. We therefore propose that the new committee, which will provide advice to UK Ministers and Health Departments, is formally established as an ANDPB.
- 12. We recommend that the Appointments Commission be directed to appoint the chair and members of the committee on behalf of the Secretary of State for Health. We will liaise with departmental solicitors and the Devolved Administrations on the preparation of the required directions.

Timing

13. Very urgent. Ministerial agreement is sought as soon as possible so that we can progress this work over the summer. We are aiming for the new committee to meet in October to consider important safety issues over the autumn, such as the possible role of further CJD risk reduction measures.

Background

14. MSBTO was initially established as a departmental expert committee (the Advisory Committee on the Virological Safety of Blood) in 1986, with a DH chair. The committee's remit evolved over the years to encompass general microbiological safety and more recently tissues and organs, but it has retained a DH chair. Members have to date been informally appointed and representation on the committee no longer properly reflects current requirements nor is the committee sufficiently independent. It is not an ANDPB.

- 15. An external review of MSBTO, commissioned at the end of 2006, recommended that a new committee be established which was more visibly independent, with the appointment of an independent chair and new membership to reflect the expertise needed. There was also a need to revise the terms of reference of the new committee and to improve the committee management procedures and processes. This would be timely as the current chair (Prof Lindsey Davies) and a number of the members are due to stand down imminently.
- 16. It has been suggested that the new committee be known as the Advisory Committee on the Safety of Blood, Tissues and Organs (ACSBTO). In addition, it proposed that the committee also formally takes on responsibility for the microbiological safety of gametes, as DH and the HFEA currently do not have access to expert advice on this issue. This has been agreed with colleagues in DH responsible for the work of the HFEA and does not cut across anything proposed in the new legislation for RATE. Proposed terms of reference for the new committee are at Annex A, together with the remit of the existing committee.

Financial Implications

17. Based on estimates from the Appointments Commission, the cost of recruiting a new committee is likely to be in the region of £40-50,000. Health Protection Division has budgeted for this work in 2007-2008.

Communications and Stakeholder Engagement

18. We have agreement in principle on the establishment of the new committee with Scottish, Welsh and Northern Irish colleagues (who will be consulting their ministers), and with the UK Blood and Transplant Services.

Risk Implications

19. The status quo is not an option mainly due to the departure of the chair and some members (para 6 above refers). If we do not set up the new committee, we will not have a committee that is recognised as appropriately constituted to provide an independent source of expert advice on important issues. The knock-on risk is that advice on safety issues related to blood, tissues and organs may not be given adequate weight by the blood, tissue and transplant communities, and public and stakeholder confidence may not be maintained.

20. It is likely that the outcome of Lord Archer's inquiry on contaminated blood and blood products will underline the importance of having transparent and robust advisory arrangements in place.

Conclusion

21. We recommend that you agree to the proposal to formally establish ACSBTO as an independent ANDPB and that the Appointments Commission should be directed to appoint the chairman and members of that committee.

William G Connon Head of Blood Policy

Copied to:

Richard Kelly

Greg Hartwell

David Harper

Elizabeth Woodeson

Lindsey Davies

Ailsa Wight

Neil Ebenezer

Gareth Jones

Triona Norman

Rowena Jecock

Peter Bennett

Tim Gordon

Zubeda Seedat

Aileen Keel

Sylvia Shearer

Elizabeth Mitchell

Cathy White

Liz Kendall

Mathew Swindells

Paul X Richards

Paul Corrigan

Annex A: Draft Terms of Reference for the proposed Advisory Committee on the Safety of Blood, Tissues and Organs (ACSBTO)

"The Committee will advise Ministers of the UK Government and the Devolved Administrations as well as UK Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing advice on the microbiological safety of gametes, in liaison with the Human Fertilisation and Embryology Authority (HFEA). The Committee will provide independent advice on risk management for Ministers and UK Health Departments to consider."

In formulating its advice, the Committee will:

- take into account sufficiency of supply, and the need to maintain adequate supplies of blood, cells (including gametes), tissues and organs of appropriate quality;
- consider the efficacy of transfusion / transplantation and consider the cost-effectiveness of interventions, including the introduction of new safety measures and/or the reduction, phasing out or withdrawal of current measures.
- interpret and where appropriate, commission risk assessments from a wide range of sources, including DH and HPA Analysts, UK Blood Services, other advisory committees such as SEAC, and independent researchers
- take full account of scientific uncertainty and assumptions used in reaching conclusions, and clearly convey the nature and extent of such uncertainties with its advice.
- identify where research to reduce uncertainty is most urgently required, and where possible identify specific research needs.
- monitor and influence the EU Directives on Blood, cells, tissues and organs to ensure that the guidance of the committee is consistent with the directives in conjunction with the relevant competent authorities.
- consider the potential impact of its advice on both donors and recipients.

Terms of Reference for the existing advisory committee on the Microbiological Safety of Blood, Tissues and Organs for transplantation (MSBTO)

"To advise the Health Departments of the UK on measures to ensure the microbiological safety of blood, tissues and organs for transplantation.

In making recommendations in relation to blood, the Committee will bear in mind the need for maintaining an adequate supply of blood of appropriate quality for both immediate use and for plasma processing."