



# Transplantation & Blood Transfusion

## Contribution of the European Union to improve transplantation and blood transfusion practices in Europe

Ernest Lluch Room, Ministry of Health,  
Social Services and Equity, Madrid, Spain  
27<sup>th</sup> and 28<sup>th</sup> of June 2013

### SUMMARY AND OBJECTIVE:

**Addressed to** European written press (major daily newspapers, health specialist press, internet news). For this event, the European Commission will invite 25-30 journalists from all over Europe. The event will also be open to the public health authorities, health-care professionals, patient associations and the interested public upon prior registration.

**Objective:** To communicate the results achieved by the projects funded by the European Union (EU) in the areas of the safety and quality of substances of human origin (SOHO), including organs, tissues, cells, blood and blood derivatives; and to focus on the projects' impact on the daily life of EU citizens and the everyday activity of hospitals around the EU.

**Ultimately, via the event,** EU citizens will be better informed on the impact of the EU SOHO projects on their daily lives and also learn about the efforts developed by the EU and its Member States (MS) to ensure the highest level of care and attention in this area.

**Organised by** the Executive Agency for Health and Consumers (EAHC) and the Directorate General for health and Consumers (DG SANCO) of the European Commission, jointly with the Spanish National Transplant Organisation (ONT), Ministry of Health, Social Services and Equality.

**Background information:** Since 2003, about 48 projects have been funded by the EU in this field. The activities include, among others, the exchange of best practices, standards for inspection, manuals, registers and training workshops. This press event aims to present these activities and to illustrate how the outcomes of those projects have concretely shaped the safety of patients and donors in Europe, and professional standards and practices. During the event, EAHC will launch the "SOHO brochure", which summarizes and highlights the results and impact of all the projects developed or under development.

These projects have further contributed to the transposition and harmonized implementation of the 3 major Directives in the field of SOHO, namely (1) Directive 2002/98/EC on "standards of quality and safety for the collection, testing, processing, storage and distribution of **human blood and blood components**", (2) Directive 2004/23/EC on "standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of **human tissues and cells**"; and (3) Directive 2010/45/EU on "standards of quality and safety of **human organs intended for transplantation**".

**Acknowledgement:**

The meeting is kindly hosted and supported by the Spanish Ministry of Health, Social Services and Equality- Government of Spain.



*Simultaneous English-Spanish translation is offered during the meeting*

**PRELIMINARY AGENDA**

Madrid, 27-28 June 2013

**Day 1 Thursday 27 June 2013, 11:30 – 18 :35**

**11:30 – 11:40 Opening**

Dr Jacques Remacle, Head of Health Unit, Executive Agency for Health and Consumers, European Commission (EAHC)

**11:40 – 12:00 Welcome note**

Ms Ana Mato Adrover, Spanish Minister of Health, Social Services and Equality, Spain (tbc)

**12:00 – 12:30 European actions in the field of transplantation & blood transfusion**

Dr Andrzej Jan Rys, Director for Directorate Health Systems and Products, DG SANCO, European Commission and

Dr Stefaan Van Der Spiegel, Unit on Substances of Human Origin and Tobacco control, DG SANCO, European Commission

**12:30 – 12:50 The added value of sharing lessons and experiences among European Union Member States**

Dr Rafael Matesanz, Director Organización Nacional de Trasplantes, Ministry of Health, Social Services and Equality, Madrid, Spain

**12:50 – 13:05 WHO initiatives for medical products of human origin: the value of EU experiences**

Dr Luc Noel and José Ramón Núñez, World Health Organization, Geneva, Switzerland (tbc)

**13:05 – 13:25 A patient's view of organ donation and transplantation**

Ms Raffaella Bruno-Pinto, Brussels, Belgium

**13:25 – 13:45 A journalist's experience: "Waiting for a chance, healthy in the soul"**

Ms Erzsebet Fazekas, Journalist for medical issues for Hungarian newspapers and magazines, Budapest

**13:45 – 13:50 Overview on the sessions of the meeting**

Dr Jacques Remacle, Head of Health Unit, Executive Agency for Health and Consumers, European Commission (EAHC)

**13:50 – 14:00 Questions and answers****14:00 – 15:00 Lunch and Coffee break**

**15:00 – 16:30**

### **Session 1: The gift of life**

Session chaired by: Dr Stefaan Van Der Spiegel, Unit on Substances of Human Origin and Tobacco control, DG SANCO, European Commission

*Summary: Living donations are key for transfusion and transplantation therapies. The living donor's safety and health therefore needs to be ensured. This session focuses on how living organ donors are protected as well as on how safety and availability of blood and blood components need to be balanced. The session also illustrates how to make best use of scarce donations.*

Presentations:

- **Introduction to the session**
- **Managing the supply and demand of blood: working with donors and with doctors (DOMAINE & EU-OBU)**  
Dr Wim de Kort, Director Donor Services, Sanquin Blood Bank, Nijmegen, Netherlands with support from the Scottish National Blood Transfusion Service, Edinburgh, UK (15 min)
- **The protection of living organ donors: progress in the EU (EULID, ELIPSY, COORENOR)**  
Dr Ana Menjívar, Researcher and Project Co-ordinator, Hospital Clínic de Barcelona - IDIBAPS, Barcelona, Spain (15 min)
- **Following up on living organ donors: registries of living organ donors in Europe (ACCORD, EULID)**  
Dr Kirsten Ooms, Dutch Transplantation Foundation, The Netherlands (15 min)
- **Optimizing the worldwide use and availability of haematopoietic stem cells (bone marrow, cord blood) (POSEIDON)**  
Dr Candide Font-Sala, Direction Médicale et Scientifique, Agence de la Biomédecine, Saint-Denis La Plaine Cedex, France (15 min)
- **Questions and answers (30 min)**

**16:30 – 17:00**

**Coffee break**

**17:00 – 18:25**

### **Session 2: Raising awareness among the population of the need for Organ and Blood Donation**

Session chaired by: Dr Olivier Huot, Head of the organ & tissues allocation platform, Agence de la Biomédecine, Saint-Denis La Plaine Cedex, France

*Summary: There is a continuous need to raise awareness for organ and blood donation at various levels and on various occasions. Proactive communications, such as the World Blood Donor Day or the European Organ Donation Day, help build public trust in donation. Reactive communications are needed to maintain trust in moments of crisis. This session further illustrates the need for the media and the importance of their relationship with transplantation authorities.*

Presentations:

- **Introduction to the session**
- **The key role of media in public engagement: lessons learnt in organ transplantation (reference to EU journalist workshops)**  
Dr Rafael Matesanz, Director Organización Nacional de Trasplantes, Ministry of Health, Social Services and Equality, Madrid, Spain (15 min)

- **The need for public trust in donation: proactive communications (World Blood Donor Day, European Organ Donation Day)**

Dr Neelam Dhingra-Kumar, Coordinator Blood Transfusion Safety (BTS) Department for Health Systems Policies and Workforce, World Health Organization, Geneva, Switzerland (10 min) (tbc)

Dr Marta López Fraga, Researcher, European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe, Strasbourg, France (10 min)

- **Maintaining trust in moments of crisis: transparency and accuracy**

Dr Axel Rahmel, Medical Director at Stichting Eurotransplant, Leiden, the Netherlands (15 min)

- **Learning to communicate and raise public awareness: EU-level support (Toolkit from EDD, FOEDUS)**

Dr Danica Avsec-Letonja, Director Slovenija-transplant, Ljubljana, Slovenia, with support from Dr Thomas Breidenbach, Directing Medical Doctor, Deutsche Stiftung Organ-transplantation, Munich, Germany (15 min)

- **Questions and answers (20 min)**

**18:25 – 18:35**

**Summary of the Day**

Dr Jacques Remacle, Head of Health Unit, Executive Agency for Health and Consumers, European Commission (EAHC)

**18:35 – 20:00**

**Optional Interviews/Discussions**

Opportunity to do press interviews with project coordinators or European Commission representatives and poster discussions with projects coordinators.

09:00 – 09:10

**Introduction to the second day**

Dr Jacques Remacle, Head of Health Unit, Executive Agency for Health and Consumers, European Commission (EAHC)

09:10 – 10:40

**Session 3: Organ donation and transplantation: making it happen**

Session chaired by: Dr Rafael Matesanz, Director Organización Nacional de Trasplantes, Ministry of Health, Social Services and Equality, Madrid, Spain

*Summary: Several activities are undertaken within and between Member States to maximise donation from deceased donors and ensuring quality and safety standards. These range from appropriately training professionals, to facilitate the identification of possible donors through the collaboration between Intensive Care and Transplant co-ordinators. This session illustrates the advances that have been possible by sharing expertise throughout the European Union in recent years.*

Presentations:

- **Introduction to the session**
- **Placing donation at the end-of-life in intensive care in Europe (DOPKI, ACCORD)**  
Prof Chris Rudge, National Clinical Director for Transplantation, Dept of Health, London 2008-2013 (15 min)
- **Transplant coordinators as the cornerstone: Training key professionals (ETPOD and Train the Trainers)**  
Dr Xavier Guasch, TPM-DTI Foundation and University of Barcelona, Barcelona, Spain (10 min)  
Dr Rosario Marazuela, Organización Nacional de Trasplantes, Ministry of Health, Social Services and Equality, Madrid, Spain (10 min)
- **Reducing risks, improving quality and exchanging organs across borders (MODE, COORENOR, ACCORD, FOEDUS)**  
Prof Alessandro Nanni Costa, Director Centro Nazionale Trapianti, National Public Health Institute, Rome, Italy (15 min)
- **Outcomes of transplantation in Europe (EFRETOS)**  
Dr Axel Rahmel, Medical Director at Stichting Eurotransplant, Leiden, Netherlands (15 min)
- **Questions and answers (25 min)**

10:40 – 11:00

**Coffee break**

11:00 – 12:45

#### Session 4: Addressing Quality and Safety in blood, tissues and cells

Session chaired by: Prof Alessandro Nanni Costa, Director Centro Nazionale Trapianti, National Public Health Institute, Rome, Italy

*Summary: The quality and safety of blood, tissues and cells require a lot of continuous efforts from actors and authorities involved. Safety and quality are a daily concern for actors in the field and European-wide standards ensure the same level of quality and safety throughout Europe. Inspections are a central tool from the oversight perspective by authorities and mutual learning between authorities a key factor. Furthermore, this session highlights the key tools to react on trafficking and fraudulent activities.*

Presentations:

- **Introduction to the session**
- **Safety and quality – a daily concern for actors in the field (Euro-GTPs)**  
Dr Esteve Trias, Transplant Services Foundation, Barcelona, Spain (tbc) (15 min)
- **Ensuring there is safety and quality of tissues and cells – the oversight perspective by authorities (EUSTITE, SOHO V&S, EURO CET)**  
Dr Deirdre Fehily, Italian National Transplant Centre, Italian National Institute of Health, Rome, Italy (15 min)
- **Improving the safety of blood donations by European wide inspections (EU-Blood-Inspection, CATIE)**  
Prof Christian Seidl, Vice Medical Director, Institute of Transfusion Medicine and Immunohaematology, Red Cross Blood Donor Service Baden-Württemberg - Hessen, Frankfurt/Main, Germany (15 min)
- **Building and sharing European standards for the quality and safety of transfusion and transplantation (Council of Europe, ODEQUS )**  
Dr Marie-Laure Hecquet, Researcher, Department of Biological Standardisation, European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe, Strasbourg, France (10 min)  
Dr Xavier Guasch, TPM- DTI Foundation and University of Barcelona, Barcelona, Spain (10 min)
- **Reacting on trafficking and fraudulent activities (SoHO V&S)**  
Dr Fewzi Teskrat, Special Advisor for Human Products, Agence française de sécurité sanitaire des produits de santé (AFSSaPS), Saint Denis, France (tbc) (15 min)
- **New traceability and vigilance tools at EU-level (EURO CET128, Rapid Alert Platforms)**  
Dr Stefaan Van Der Spiegel, Unit on Substances of Human Origin and Tobacco control, DG SANCO, European Commission (10 min)
- **Questions and answers (15 min)**

**12:45 – 13:00**

**Key-note speech: The road ahead – Future perspectives and activities in Legislation and Co-operation between European Member States (tbc)**

Dr Andrzej Jan Rys, Director for Directorate Health Systems and Products, DG SANCO, European Commission

**13:00 – 13:10**

**Closing remarks and Launch of the brochure**

Dr Jacques Remacle, Head of Health Unit Executive Agency for Health and Consumers (EAHC), European Commission

**Optional Interviews/Discussions**

Opportunity to do press interviews with project coordinators or EC representatives and poster discussions with projects coordinators.

**13:30**

**End of meeting**

## Projects to be presented during the meeting

Acronym	Title
<b>Projects on Blood and blood components</b>	
EU-Q-Blood-SOP	Development of a pan-European standard operating procedure (SOP) methodology reflecting European best practice within the area addressing the quality and safety of blood <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2004217">http://ec.europa.eu/eahc/projects/database.html?prjno=2004217</a> <a href="http://www.eu-q-blood-sop.de/">http://www.eu-q-blood-sop.de/</a>
EuBIS	Development of pan-European standards and criteria for the inspection of blood establishments (EU-Blood-Inspection) <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2004217">http://ec.europa.eu/eahc/projects/database.html?prjno=2004217</a> <a href="http://www.eu-q-blood-sop.de/">http://www.eu-q-blood-sop.de/</a>
DOMAINE	Creating a safe and sufficient donor population in Europe: comparing and recommending good donor management practice <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2007202">http://ec.europa.eu/eahc/projects/database.html?prjno=2007202</a> <a href="http://www.domaine-europe.eu/">http://www.domaine-europe.eu/</a>
EUOBU	EU Optimal Blood Use Project <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2006209">http://ec.europa.eu/eahc/projects/database.html?prjno=2006209</a> <a href="http://www.optimalblooduse.eu/">http://www.optimalblooduse.eu/</a>
QS-TS Programme	Quality Systems in the Blood Transfusion Field including inventory Visits, Audits and Proficiency Testing Scheme (PTS) studies <a href="http://www.edqm.eu/">http://www.edqm.eu/</a>
CATIE	Training sessions for inspectors in the field of blood and blood components <a href="http://www.catie-europe.eu/">http://www.catie-europe.eu/</a>
<b>Projects on Human tissues and cells for transplantation</b>	
EUROCET	European registry for organs, tissues and cells project <a href="http://www.eurocet.org/">http://www.eurocet.org/</a> <a href="http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&amp;project_ref=ETEN-517417">http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&amp;project_ref=ETEN-517417</a>
EUSTITE	European Union standards and training for the inspection of tissues establishments <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2005204">http://ec.europa.eu/eahc/projects/database.html?prjno=2005204</a> <a href="http://www.sohovs.org/soho/mod/resource/view.php?id=43">http://www.sohovs.org/soho/mod/resource/view.php?id=43</a>
POSEIDON	Promoting optimisation, safety, experience sharing and quality implementation for donation organisation and networking in unrelated haematopoietic stem cell transplantation in Europe <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2006210">http://ec.europa.eu/eahc/projects/database.html?prjno=2006210</a>
Euro-GTPs	European Good Tissue Practices <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2007207">http://ec.europa.eu/eahc/projects/database.html?prjno=2007207</a> <a href="http://eurogtps.com/">http://eurogtps.com/</a>

SOHOV&S	Vigilance and Surveillance of Substances of Human Origin <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20091110">http://ec.europa.eu/eahc/projects/database.html?prjno=20091110</a> <a href="http://www.sohovs.org/soho/">http://www.sohovs.org/soho/</a>
EUROCET128	Building reference compendia for the application of a single European coding system for tissues and cells <a href="http://www.eurocet128.eu">http://www.eurocet128.eu</a>
<b>Projects on Organ donation and transplantation</b>	
DOPKI	Improving the knowledge and practice of Organ Donation <a href="http://ec.europa.eu/research/fp6/ssp/dopki_en.htm">http://ec.europa.eu/research/fp6/ssp/dopki_en.htm</a>
ETPOD	European Training Program on Organ Donation <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2005205">http://ec.europa.eu/eahc/projects/database.html?prjno=2005205</a> <a href="http://etpod.il3.ub.edu/">http://etpod.il3.ub.edu/</a>
EULID	European Living Donation and Public Health <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=2006211">http://ec.europa.eu/eahc/projects/database.html?prjno=2006211</a> <a href="http://www.eulivingdonor.eu">http://www.eulivingdonor.eu</a>
EFRETOS	European Framework for the Evaluation of Organ Transplants <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20081101">http://ec.europa.eu/eahc/projects/database.html?prjno=20081101</a> <a href="http://www.efretos.org">http://www.efretos.org</a>
ELIPSY	European Living Donor Psychological Follow-up <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20081104">http://ec.europa.eu/eahc/projects/database.html?prjno=20081104</a> <a href="http://www.eulivingdonor.eu/elipsy/">http://www.eulivingdonor.eu/elipsy/</a>
EDD	Developing Guidelines for the Organisation of a Public Organ Donation Day <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20081109">http://ec.europa.eu/eahc/projects/database.html?prjno=20081109</a> <a href="http://www.europeandonationday.org/">http://www.europeandonationday.org/</a>
ODEQUS	European Quality System Indicators and methodology on Organ Donation <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20091108">http://ec.europa.eu/eahc/projects/database.html?prjno=20091108</a> <a href="http://www.odequs.eu/">http://www.odequs.eu/</a>
COORENOR	Coordinating a European Initiative among National Organizations for Organ Transplantation <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20091103">http://ec.europa.eu/eahc/projects/database.html?prjno=20091103</a> <a href="http://www.coorenor.eu/">http://www.coorenor.eu/</a>
MODE	Mutual Organ Donation and transplantation Exchanges: Improving and developing cadaveric organ donation and transplantation programs (Joint Action) <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20102101">http://ec.europa.eu/eahc/projects/database.html?prjno=20102101</a> <a href="http://www.mode-ja.org">http://www.mode-ja.org</a>
ACCORD	Achieving Comprehensive Coordination in Organ Donation throughout the European Union (Joint Action) <a href="http://ec.europa.eu/eahc/projects/database.html?prjno=20112102">http://ec.europa.eu/eahc/projects/database.html?prjno=20112102</a> <a href="http://www.accord-ja.eu/">http://www.accord-ja.eu/</a>
ETC	European Training Course for Trainers in Transplant Donor Coordination in the European Union <a href="http://www.etc.iavante.es/">http://www.etc.iavante.es/</a>