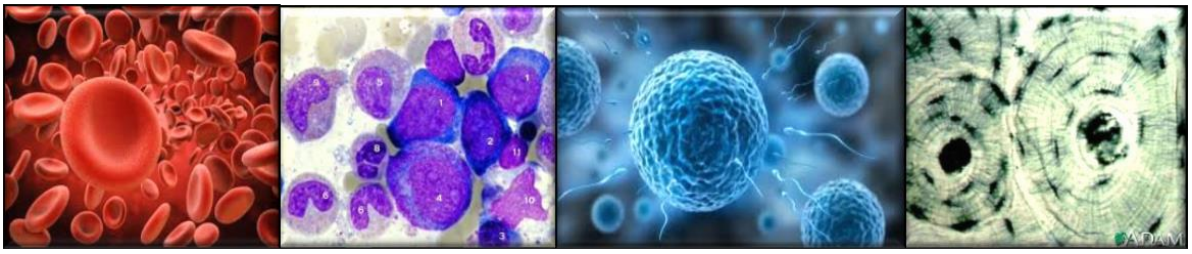

CONFERENCE ON THE EVALUATION OF THE EU LEGISLATION ON BLOOD, TISSUES AND CELLS

28 October 2019

PANELLISTS

PANEL 1

Philippe VANDERKERCKHOVE

Representing the European Blood Alliance

Philippe Vandekerckhove, M.D./PhD, pathologist, is the CEO of the Belgian Red Cross-Flanders, and associate professor at the Faculty of Medicine of the Universities of Leuven (Belgium) and Stellenbosch (South Africa). He holds non-executive positions as president of the European Blood Alliance and president of GAP (Global Advisory Panel (GAP) on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies). He has published about 100 articles mainly in the field of immunology, hematology, blood banking and evidence-based medicine.

Jacinto SANCHEZ IBAÑEZ

Representing the European Society of Tissue and Cell Banks

CURRENT POSITION:

Director A Coruña University Hospital Tissue Establishment, Spain

- Member of the European Association of Tissue Banking since 1995. Current President
- Founding partner of the Spanish Association of Tissue Banking.
- Expert for human tissues of the International Atomic Energy Agency
- Chair of the 4th edition to the Guide of Quality and Safety of Tissues and Cells for Human application

EMPLOYMENT

Attending Physician General Surgery. Hospital Provincial de Santiago. Santiago de Compostela.

Transplant Procurement Manager (Transplant Services Foundation). Hospital Clínic Barcelona.

Responsible for the Human Tissue Transplant Program. Hospital Juan Canalejo. A Coruña.

Director of the Transplant Coordination Office in Galicia. Santiago de Compostela.

Jurgen Kuball

Representing the European Society for Blood and Marrow Transplant

Prof. Dr. Jürgen Kuball received his medical degree as hematologists at the University of Mainz, Germany, and was further trained at the Fred Hutchinson Cancer Center in Seattle, WA, USA. Prof. Kuball joined the Department of Hematology at the University Medical Center in Utrecht in 2007 as hematologists and immunologist. He became a VIDI-laureate in 2010 and chairs the section applied & tumor-immunology within the laboratory of translation immunology. Since 2013 he is chairing the Department of Hematology (adults). His clinical activities are focusing on treating patients with hematological malignancies including stem cell transplantation. His clinical-translational efforts and patient care are driven by his role as Director of the Bone Marrow Transplantation Program at the University Medical Center Utrecht, as well as active membership of the Leukemia working party and stem cell working party of HOVON. His current laboratory activities are focusing on the understanding of innate immune cells and their receptors to recognize malignant cells and virally infected cells as well as the genetic engineering of a transplant.

Diego Ponzin

Representing the European Eye Bank Association

Diego Ponzin, MD is Medical Director and Corneal Consultant of the Veneto Eye Bank Foundation in Venice, Italy. His clinical fields of interest include the ocular surface and corneal diseases and infections, corneal transplantation, cornea biology, storage and selection for transplantation.

He obtained his medical degree at the University of Padua, Italy and his post-doctoral diploma in Ophthalmology at the University of Udine, Italy.

He has been:

Research Associate at the Department of Immunology of the FIDIA Research Laboratories in Padua;

Expert for eye banking of the Consulta Nazionale Trapianti, Rome;

Fellow at the Ophthalmic Division, Hospital Umberto I, Venice, Italy;

Visitor at: the Bristol Eye Bank, Bristol Eye Hospital, Bristol (UK), the Manchester Eye Bank, Manchester Royal Eye Hospital, Manchester (UK), the Cornea Bank, The Netherlands Ophthalmic Research Institute (The Netherlands).

Lecturer in Ophthalmology, University of Padua, Italy.

He received a Fellowship in Ophthalmology granted by the Veneto Eye Bank Foundation, Ophthalmic Division, Hospital Umberto I, Venice, Italy.

He was Research Associate in Neuroimmunology, Dept. of Pathology, Albert Einstein College of Medicine, New York, U.S.A., and Research Associate in Immunology, Pathology Laboratory, ENEA C.R.E., Casaccia, Rome, Italy.

Dragoslav Domanovic

Education and degree: MD, PhD

Specialisation:

- Specialist in transfusion medicine

Working experiences at the National institute for transfusion medicine Ljubljana, Slovenia:

- Head of the blood bank
- Head of the cord blood bank
- Collection, processing and storage of peripheral blood stem cells
- Processing, and storage of platelet gel and amniotic membranes

Current position:

- Senior Expert Vigilance and Traceability of Tissues and Cells of Human Origin
- European Centre for Disease Prevention and Control, Stockholm, Sweden

Current expertise and areas of interest

- Scientific advice in transmission of communicable diseases through substances of human origin
- Response to outbreaks and risk assessments of infectious diseases transmission through substances of human origin
- Preparedness for safety of supply with substances of human origin
- Epidemiology of donor derived infection
- Emerging infectious diseases
- Prevention and control of blood borne viruses – HIV, hepatitis B and C

PANEL 2

Alice SIMONETTI

Representing the International Federation of Blood Donors

Alice Simonetti, 30 years old, from Italy, is a member of the Executive Council of the International Federation of Blood Donor Organizations (IFBDO/FIODS), created in 1955 and nowadays including more than 80 countries in 4 continents promoting the message of Voluntary and Non Remunerated Blood Donation, founding partner of the World Blood Donor Day. In the Federation she also serves as Secretary of the European Continental Committee. In her home country she's the head of International Relations of the Italian Association of Voluntary Non remunerated Blood Donors (AVIS).

http://www.fiods-ifbdo.org/

Kersti LUNDIN

Representing the European Society for Human Reproduction and Embryology

Dr Kersti Lundin started as an embryologist and researcher in 1991 at Reproductive Medicine, Sahlgrenska Hospital, Gothenburg, where she became Laboratory Director in 1997 and Associate Professor in 2004.

She has published a large number of articles and chapters in scientific journals and books and presented at many international congresses. She is a lecturer on courses and workshops throughout Europe, and has been involved in the start and running of both Swedish and Nordic IVF Laboratory Associations.

Dr. Lundin has been a coordinator of the ESHRE Embryology

certification committee, coordinator of the ESHRE Special Interest Group of Embryology, and chairman of ESHRE 2015-2017.

Matthias GESSNER

Representing the European Plasma Association

- Chair of European Plasma Alliance (EPA) and Austrian Plasma Collectors' Association (IG Plasma), member of the Blood Advisory Committee for the Austrian Minister of Health.
- Sr. Director, BioLife European Operations, Takeda
- Ph.D. in Molecular Biology from University of Kaiserslautern, Germany
- Started in the plasma industry at Immuno AG, Vienna as Research Associate for the optimization and development of routine NAT testing for plasma. Today at Takeda responsible for BioLife's European Operations including 31 plasma centers in Austria, Czechia, Hungary, the European serology and NAT plasma screening lab, and the central European plasma logistics center and warehouse in Vienna.

Lydia FOEKEN

Representing the World Marrow Donors Association

I joined WMDA in February 2003 and became managing director in January 2014. My key priority is to facilitate international transplants by developing a global network. Inspired by the passion and commitment of WMDA's members, I work to build on the pioneer work of Prof. Dr. Jon J. van Rood and secure it for a successful future.

At WMDA, I work with a wonderful team, enthusiastic members and corporate supporters, as well as with regulatory bodies and professional societies. I see it as my role to deliver WMDA's vision, and to strive that each patient in the world finds the perfect match.

PANEL 3

Lea JOOS

Representing the Inspectors Expert Sub-group (IES) of the Commission's Expert Group on Substances of Human Origin (Competent Authorities)

Lea Joos is a pharmacist working for the local inspectorate Government of Upper Bavaria in Munich as inspector in the tissues and cells sector. Since 2018 she is representing Germany as a member of the Expert Sub-group on Inspections in the Blood Tissues and Cells Sector (IES).

Johanna (Jo) WIERSUM-OSSELTON

Representing the Vigilance Expert Sub-group (VES) of the Commission's Expert Group on Substances of Human Origin (Competent Authorities)

Jo Wiersum, née Osselton, MD, PhD, is a specialist in community medicine working in blood donor medicine and in hemovigilance and biovigilance in The Netherlands. After qualifying she worked for some years in Britain and then in the Republic of Guinea, West Africa. She has worked for the Dutch blood service Sanquin since 1996 where she is a member of the project group for prevention of complications of blood donation.

Jo Wiersum has been the national medical coordinator of the TRIP (Transfusion and Transplantation Reactions in Patients) Hemovigilance and Biovigilance Office since it began in 2002. She is a rapporteur member of the Vigilance Expert Subgroup of the Competent Authorities for Blood, Tissues and Cells. In her work the harmonisation of definitions and the quality of haemovigilance systems form major themes.

Marta LÓPEZ FRAGA

Scientific Officer in charge of the transplantation activities at the European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe.

She received her M.Sc. in Biology from the Complutense University of Madrid and a Ph.D. in Immunology from the Autónoma University of Madrid (Spain). She did postdoctoral work at La Jolla Institute for Allergy and Immunology (USA) and in 2006 joined Neurome Inc./University of California Riverside (USA) to work on the development of targeted mucosal vaccine delivery technologies for the Bill and Melinda Gates Foundation. In 2008, she joined Sylentis (Spain) to work on the development of innovative treatments against inflammatory diseases.

Since 2011 she coordinates the European Committee on Organ Transplantation (CD-P-TO), the Steering Committee in charge of the transplantation activities at the Council of Europe. The CD-P-TO actively promotes the non-commercialisation of organ, tissue and donation, the fight against trafficking and the development of ethical, quality and safety standards in the field.

Eoin McGrath

Representing the Consortium Representative SoHO associations (CoReSOHO: EBA, EEBA, EBMT and EATCB)

Mr. Eoin McGrath is the JACIE Operations Manager for the European Society for Blood and Marrow Transplantation (EBMT) based in Barcelona, Spain since 2002. JACIE is the long-standing EBMT accreditation scheme for hematopoietic stem cell transplantation programmes. He also coordinates EBMT's interactions with EU bodies including DG SANTÉ and EMA and has participated as a member of the External Assessment Board for EU joint actions including ARTHIQS and VISTART and is rapporteur for HSCT for WP6 of the GAPP Joint Action.

Daniel MENENDEZ

Auditor, Unit 5, Directorate F
DG SANTE, European Commission
range, Kiltale, Co. Meath,Ireland

PANEL 4

Giancarlo LIUMBRUNO

Representing the GAPP Joint Action

Current position Since 2015 Director General, Italian National Blood Centre, Rome Since 2015 National blood and blood components competent authority on behalf of the Italian Ministry of Health

Education 1995 Certificat d'Université d'Enseignement Européen de Transfusion Sanguine (Louis Pasteur University, Strasbourg, France). 1993 Specialisation in Clinical Pathology - Immunohaematology (University of Pisa, Italy). 1985 MD degree (University of Pisa, Italy).

Owen BAIN

Representing the International Society for Cell Therapy

Dr Owen W Bain, MRPharmS MRes EngD is the Head of Quality Control and trainee QP at the Centre for Cell, Gene and Tissue Therapeutics (CCGTT), Royal Free Hospital, London. Dr Bain is also a qualified pharmacist and previously worked in Product Development at GlaxoSmithKline. Having obtained an engineering doctorate in the Department of Biochemical Engineering, UCL, he came to work at the CCGTT.

The CCGTT is the foremost academic facility for the manufacture of cell, gene and tissue medicines, in Europe. It is licensed by the MHRA and HTA for the procurement, production & storage of human cells & tissues for therapy and ATMP manufacture.

Annie HUBERT

Representing the Alliance for Regenerative Medicine

Annie Hubert, Senior Director of European Public Policy, Alliance for Regenerative Medicine.

Annie brings over 30 years of experience in European regulatory and government affairs, pricing, reimbursement and market access to the ARM Team.

She came to ARM via the membership merger with the former Alliance for Advanced Therapies in the fall of 2014, where she had served as Director of Public Affairs since November 2013. She is also Managing Director of ESAH (Expert Services and Advice in Healthcare), a consulting company founded in 2012. In June 2012, Annie founded and directed Co-ACT, an association for small and medium-sized enterprises developing advanced therapies in Belgium.

Between 2001 and 2011, Annie worked at Amgen as Corporate Affairs Director for the BeLux affiliate and then as European Government and Public Affairs Director.

Esteve TRIAS

Representing the Consortium Representative SoHO associations (CoReSOHO: EBA, EEBA, EBMT and EATCB)

Esteve is a Medical Doctor with more of 20 years experience working on the field of Substances of Human Origin. He started his activity in this field working in the organ transplantation area in the hospital clinic in Barcelona and leaded the developing of the Catalan Tissue Establishment, first linked to the Hospital - TSF and later to the Blood Bank. He also develop the Advanced Therapies Unit in the Hospital Clinic in 2010, where he is still currently the Director leading new developments in the area.

Esteve has been member of the Committee of Advanced Therapies - CAT of the European Medicines Agency as professionals representative and leading different European projects and initiatives like the EuroGTP -I and II projects, as well as a Twinning on the field in Croatia. He is Representing Catalan Health Department in national and international committees. Past President

of EATCB and current Secretary of EEBA, was one of the founders of the Consortium of Substances of Human Origin. Currently he combines his position in the Clinic Hospital with the Strategic Management of an Innovation Platform on Health at Leitat Technological Center.

PANEL 5

John PREVOT

Representing the International Patient Association for Primary Immune Deficiencies (IPOPI) and the Platform of Plasma Protein Users (PLUS)

Johan Prevot has worked in the healthcare sector for 19 years in the field of patient advocacy and health policy.

Mr. Prevot is the Executive Director of the International Patient Organisation for Primary Immunodeficiencies (IPOPI). As such he is responsible for the management and growth of IPOPI's global activities, awareness and advocacy campaigns as well as the strengthening of IPOPI's national member organisations network.

Johan Prevot is a Board member of the European Reference Network on Rare Primary Immunodeficiency, Autoinflammatory and Autoimmune diseases (ERN-RITA), Health First Europe (HFE) and the RECOMB research programme. He is also a Steering Committee Member of the Platform of Plasma Products Users (PLUS). Johan Prevot previously worked as Director of Health Policy Europe for the Plasma Protein Therapeutics Association (PPTA), a trade association in the field of plasma protein therapies.

Johan Prevot has throughout his career been an advocate for improving patient access to early diagnosis and treatment in the field of rare diseases including primary immunodeficiencies, haemophilia and alpha 1 antitrypsin deficiency among others. Access to diagnosis and treatment for primary immunodeficiencies and other rare plasma related disorders varies greatly from country to country and many people living with these conditions in developing countries still nowadays can not access their life enhancing and/or life saving therapies. Mr Prevot has and continues to work closely with other stakeholder organisations sharing common objectives and priorities.

Jan BULT

Representing the Plasma Protein Therapeutics Association

Jan M. Bult, President Emeritus, Plasma Protein Therapeutics Association (PPTA). PPTA is a global organization and represents manufacturers of plasma protein therapies made from human plasma and through alternative (recombinant) technologies. PPTA also represents over 900 source plasma collection centers in both the USA and Europe.

Mr. Bult was President and CEO of PPTA from January 1998 to December 2018. In 2019 he is acting as President Emeritus for PPTA he was the Executive Director of the European Division. Before that he was the Executive Director of the European Division from 1995 till 1997.

Paul STRENGERS

Representing the International Plasma Fractionators Association

Paul Strengers was Medical Director of CLB Blood Bank and Director Medical Affairs at Sanquin, Plasma Products in Amsterdam.

His activities are focused on clinical transfusion medicine and sciences on plasma derived medicinal products, haemovigilance and pharmacovigilance, and blood transfusion quality, ethics and organization.

As independent consultant, he is Executive Director of IPFA, and a Member of ECBS, section Blood, of WHO. He was President of the International Haemovigilance Network and Secretary-General of the International Society of Blood Transfusion. He is Honorary Member of the ISBT and Corresponding Member of the DGTI. Publications of more than 150 scientific papers.

Nigel TALBOYS

Representing Medtech Europe

Nigel has global responsibility for Government Affairs and Public Policy for Terumo BCT.

He is Chairperson of the Public Affairs Committee, representing Industry at the European Trade Association (MedTech Europe), Chairperson of the Public Affairs Group at the Association of British HealthTech Industries (ABHI), President of the Blood Transfusion Association (BTA), a board member of MedPharmPlast, Chairperson of the regulatory committee for MedPharmPlast and a board member of the UK, Japan 21st Century Group. This groups' primary goal is to serve as a catalyst for increasing the level of mutual understanding and awareness of the political, economic, and social environments in each country.

Marie-Laure HECQUET

Marie-Laure Hecquet, BSc, MSc/Eng. D, Head of the HealthCare Section, Council of Europe/EDQM.

2007, joined the CoE/EDQM, Scientific Assistant/European Pharmacopeia Department, coordinated the elaboration of monographs on PDMPs, recombinant proteins, Monocytes Activation Test and Glycan Mapping.

2010, Scientific Programme Manager/Department of Biological, Standardisation, OMCL and HealthCare: responsible for the Blood Proficiency Testing Scheme and Quality Management programmes (EU/EDQM funded activities). Lead auditor, trainer to EU legislation, GMP, GPG and CoE Blood Guide.

2019, Head of the Healthcare Section: Blood Transfusion, Transplantation, Pharmaceutical Care, Anti-Counterfeiting, Cosmetics and Food Contact Materials activities.

Since 2014, Lecturer/European Management School, Strasbourg: European Health legislation, Public Health Standards, Quality- ,Risk- and Project Management

Member of the ISBT QM Working Party, CoE/EDQM representative at Blood Competent Authority meetings at the EC, IRCA auditor