EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

PCWP/HCWP Workshop on personalised medicines: role of patients, consumers and healthcare professionals

Speakers' biographies

Kaisa Immonen

Kaisa Immonen holds a Master of Arts (MA) in international relations and conflict analysis from the University of Kent in the United Kingdom. She has eight years' experience in European Union health policy gained firstly at the Thalassaemia International Federation, a rare-disease patient organisation in Nicosia, Cyprus and then with the European Patients' Forum (EPF), in Brussels, Belgium. She has worked for EPF for six years and has served as director of policy since 2015.

She is the co-chair of the EMA Patients' and Consumers' Working Party (HCPWP).

Gonzalo Calvo

Gonzalo Calvo is Past-Chair of the European Association for Clinical Pharmacology and Therapeutics (EACPT). He is a consultant in clinical pharmacology in Barcelona and has extensive experience both in medicines regulation, including nearly ten years as member of the Agency's Committee for Medicinal Products for Human Use (CHMP), and in learned societies.

He is the co-chair of the EMA Healthcare Professionals' Working Party (HCPWP).

Irene Norstedt

Irene Norstedt is Head of Unit for the Innovative and Personalised Medicine Unit in the Health Research Directorate in DG Research and Innovation. This Unit is focusing on personalised medicine and supports research in –omics, diagnostics, rare diseases and various aspects of personalised medicine including piloting personalised medicine in health care. She has been working with European life sciences research aspects at the European Commission since 1996. During the first 9 months of 2015 she was also Acting Executive Director for the Innovative Medicines Initiative (IMI), a public private partnership between the EC and the Pharmaceutical industry. Previous responsibilities at the EC have

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primarily focused on Small and Medium size Enterprises and industry aspects of biotechnology and health research at European level. Before starting her job in Brussels she worked for Biacore AB in Uppsala, Sweden. There she had several positions and she has also worked as Assistant Technical Attaché at the Swedish Embassy in London.

Sandra Kweder

Dr. Sandra L. Kweder was named Deputy Director of the FDA's Europe Office in the Office of International Programs (OIP), in March 2016. Prior to joining OIP, Dr. Kweder was Deputy Director, Office of New Drugs (OND) in FDA's Center for Drug Evaluation & Research (CDER), since 2002. In CDER she was an active leader of a number of initiatives, including improvements in the drug review process; modernizing nonprescription drug review; building a systematic drug shortage prevention and management program; patient-focused drug development and clinical outcomes assessment, and; the growth and development of pediatrics and maternal health as standard aspects of drug development.

Dr. Kweder was commissioned in the U.S. Public Health Service upon entering the Uniformed Services University of Health Sciences (USUHS), retiring in 2013 at the rank of Rear Admiral. Following internal medicine training at Walter Reed Army Medical Center she joined the U.S. Food & Drug Administration (FDA) in the Division of Antiviral Drugs to address the growing field of HIV drug development. She has since held a number of positions with FDA in premarket and postmarketing regulation. Until her move to London she was active in medical education as an adjunct faculty member of USUHS, training residents and medical students in Internal Medicine and utilizing her fellowship training from Brown University in Obstetric and Consultative Medicine.

Mária Judit Molnár

Maria Judit Molnar MD, PhD, Professor of Neurology, Psychiatry, Clinical Genetics, and Clinico-pharmacology, Doctor of the Hungarian Academy of Sciences is the director of Semmelweis University's Institute of Genomic Medicine and Rare Disorders, among others president of the Hungarian Medical College of Clinical Genetics, past president of the Hungarian Society of Clinical Neurogenetics, secretary of the Hungarian Society of Personalized Medicine, elected president of the Hungarian Society of Human Genetics, board member of the Neurogenetic and Neuromuscular Committee of the European Academy of Neurology. She was the vice-rector for Scientific Affairs at Semmelweis University (Budapest, Hungary) between 2012 and 2015, where she was also responsible for International Affairs. She has been adjunct professor at the Montreal Neurological Institute, McGill University, since 1999. Dr Molnar is the Facilitator of a Challenge Group of the International Consortia of Personalized Medicine initiated by the European Commission. She is the member of the steering committee of the Association of Academic Health Centers International.

Dr. Molnar is recognized as a leading expert on the diagnosis and treatment of rare neurological disorders. The Institute of Genomic Medicine and Rare Disorders lead by her offers a comprehensive state of the art, patient-centred care for patients with rare neurological disorders including genetic testing, neuropathological investigations and genetic counselling as well. Dr. Molnar's research covers a broad range of basic and clinical studies on rare neurological disorders, utilizing a broad spectrum of technologies including clinical science, histology, cytochemistry, molecular biology and genetics. She plays important role in the organization of rare disease management in Hungary and acts as an ambassador promoting the personalized healthcare. She has acted as a principle investigator for several clinical trials. She has published 1 book, 19 book chapters, 125 papers with cumulative impact factors 141, Hirsch index: 19 and more than 1100 citations. She owns 2 patents.

Luca Pani

Luca Pani, Medical Doctor, specialized in Psychiatry is an Expert in Pharmacology and Molecular Biology, and a Fellow of the National Research Council of Italy who has served as Director General of the Italian Medicines Agency (AIFA) from 2011 to 2016, with CEO roles of Regulator and Negotiator / Payer. Prof Pani is currently associated with the Faculty of the Department of Psychiatry and Behavioural Sciences at the University Of Miami School Of Medicine, in USA.

Luca Pani's professional trajectory has touched several areas of expertise from preclinical study to clinical activity as well as R&D of CNS drugs, along with a strong commitment to teaching on experimental and clinical cases. He attends at national and international regulatory activities for the European Union. During the past decade, he has prepared, evaluated and coordinated vast research projects with strategic planning and partnerships by collaborating with groups worldwide and participating in international bodies and advisory committees on innovation both at the scientific and regulatory / HTA level.

Luca Pani is Italian Alternate Member of the Committee for Human Medicine Products (CHMP); Full Member of the Scientific Advice Working Party (SAWP); participant of the Working Party on Central Nervous System (WPCNS) and he has been the Chair of both the European Union Management Board Telematic Committee (EUMBTC) and the EU Network Pharmacovigilance Oversight Group for the European Medicines Agency (EMA) in London (UK) from 2013 to 2016.

He is the author of over one hundred and fifty scientific publications, editor and author of several volumes and also a writer of successful leisure literature. He has attended over 1,000 conferences, seminars, workshops and national and international roundtables as an invited speaker.

Robert Hemmings

Rob Hemmings is a professionally qualified medical statistician. He has been with the Medicines and Healthcare products Regulatory Agency (previously Medicines Control Agency) for more than 15 years and heads the group of medical statisticians. Much of Rob's time is spent educating medical colleagues in the importance and artistry of clinical trial statistics; their use in proof and in obfuscation. Rob currently holds the following positions within the European drug regulatory system:

• CHMP member: CHMP is the body responsible for preparing the opinions of the European Medicines Agency on all questions concerning medicinal products for human use. Rob is one of the 32 voting members of this key European committee.

• Chair of the CHMP's Scientific Advice Working Party (SAWP) with responsibility for preparing advice to the pharmaceutical industry on the appropriate tests and trials to conduct in the development of a medicine for marketing authorisation. This group includes approximately 50 regulatory scientists from across the European regulatory network and handles approximately 400 scientific advice / protocol assistance and qualification of biomarker procedures each year.

• Rob is also a member of CHMP's Biostatistics working party with responsibility for giving advice on matters relating to clinical trial methodology across the EU regulatory network.

Bruno Sepodes

Bruno Sepodes holds a PhD in Pharmacy (Pharmacology) by the University of Lisbon. Currently a Professor of Pharmacology and Pharmacotherapy at the Faculty of Pharmacy of the University of Lisbon, he develops his research in Pharmacology and Translational Medicine.

Presently Prof Sepodes is the Chair of the Committee for Orphan Medicinal Products (COMP) and member of the Committee of Human Medicinal Products (CHMP) and of the Committee of Advanced Therapies (CAT) at the European Medicines Agency in London.

His collaboration with the European Medicines Agency started as a member of the COMP in 2008 and followed as a member of the Patients' and Consumers Working Party during 2012.

Bruno Sepodes is an expert for the National Medicines Authority (INFARMED) and for the Veterinary General Directorate (DGV). Concerning the involvement in research projects, international collaborations include collaboration with the William Harvey Research Institute (UK) and other relevant research institutes.

He is author and co-author of more than 70 scientific publications in international journals, and more than 100 scientific communications (on pharmacology, toxicology and therapeutics), presented to national and international scientific meetings. Areas of expertise include: orphan medicinal products development and evaluation; pharmacology of inflammation; human medicines evaluation, general and special toxicology and non-clinical drug development.

Margarida Menezes Ferreira

Margarida Menezes Ferreira graduated in Biology at the Faculty of Sciences of the University of Lisbon. She had her PhD degree in Medical Biochemistry at the Aix-Marseille II University in France 1981 and did a post-graduate research in molecular endocrinology at the National Institutes of Health USA until 1984. Since January 1996 she is part of INFARMED, the Portuguese regulatory authority for medicines and health products having developed the strategic plan for the installation of the Biologics, Biotechnology and Microbiology Departments of the National Laboratory for the Control of Medicines and Health Products and coordinated its implementation until 2001. From 1999 to 2001 she was acting Director of the National Control Laboratory for Medicines and Heath Products (OMCL). Since 1999 to the present she has been the INFARMED appointed member of the Biologics Working Party at the European Medicines Agency (EMA).

She has participated in the drafting of European guidance and scientific advice on biological medicinal products including biotechnological and biosimilars as well as gene and cell based therapies. Starting in 2007 as guest member and subsequently as a permanent member of the Cell Products Working Party until its closure, she participated intensely in the construction of the regulatory framework and quality guidance for cell based medicinal products. Presently and since its establishment in 2009 she is the Portuguese member at the Committee for Advanced Therapies. She also collaborates as guest professor with the Faculty of Pharmacy from the University of Lisbon coordinating a chair on Advanced Therapy Medicinal Products. She is also lecturing on Regulatory aspects related to Biotechnology and Advanced Therapy Medicinal Products in several post-graduate courses from Universities of Coimbra and University of Aveiro and at the Instituto Superior Técnico /University of Lisbon in the PhD program MIT-Portugal.

Dirk Mentzer

Medical education was conducted at University hospital in Frankfurt am Main, Germany. Paediatric specialist training from 1992 till 2000 at University Children hospital in Frankfurt am Main, Royal Belfast Hospital for Sick Children, Northern Ireland. The special interest during Paediatric specialist training included Neonatology, paediatric Haematology, infectious disease and paediatric radiology. Medical dissertation defended in 1995. Appointment as a Consultant in General Paediatric in 2001 at University Children hospital in Frankfurt am Main and in Neonatology and general Paediatric at Princess Royal University Hospital in Bromley, London until August 2004. Dirk Mentzer has been employed as Head of Pharmacovigilance unit at Paul-Ehrlich-Institut in Langen, Germany since 2004. Since 2007 German member of the Paediatric Committee at the EMA and since 2013 elected Chair of Paediatric Committee at the EMA.

June Raine

Dr June Raine trained in general medicine in Oxford after completing a Masters degree by research in Pharmacology. Her interest in drug safety led to a career in medicines regulation which has spanned a number of roles in assessment, management and strategic development within the UK national authority. Appointed in 1999 to head Pharmacovigilance in the UK, she was elected in 2005 to chair the CHMP's Pharmacovigilance Working Party and in 2012 as the first chair of the Pharmacovigilance Risk Assessment Committee. She is also a member of the WHO Advisory Committee on Safety of Medicinal Products. Her special interests are in monitoring the outcomes of regulatory action, risk communication and patient involvement in the regulatory process.

Anna Bucsics

Anna Bucsics received her medical degree from the Karl-Franzens-University of Graz, Austria, where she did postgraduate research at the Department of Experimental and Clinical Pharmacology.

In 1991 she moved to Vienna where she worked as auditor for pharmaceutical expenditures at the Viennese Social Health Insurance and at the Main Association of Austrian Social Insurance Institutions. At the latter, she was Head of the Department of Pharmaceutical Affairs until the end of 2013. She is advisor to the MoCA (Mechanism of Coordinated Access to Orphan Medicinal Products, www.eurordis.org/content/moca) project, and to the MEDEV Committee (an informal group of experts from public organisations responsible for pharmaceutical reimbursement), whose speaker she was from 2001 to 2005. She has participated in European projects such as EUnetHTA, the Pharmaceutical Forum, and the Platform on Access to Medicines in Europe and as a member of the European Commission Experts Group on Rare Diseases. She is an instructor at the Department of Finance, University of Vienna, as well as Judicial Advisor (Beisitzer) at the Federal Administrative Court of Austria.

Denis Lacombe

Denis Lacombe graduated with his MD from the University of Marseilles (France) in 1988 and obtained a Master Post-Doctoral Fellowship at The Roswell Park Cancer Institute (Buffalo, NY USA) for research in pharmacology and pharmacokinetics from 1989 to 1991. From 1991 to 1993, he worked as a Clinical Research Advisor in charge of the development of a new drug in oncology in the pharmaceutical industry.

Dr Lacombe joined the EORTC in 1993 as a research fellow and quickly became a very active and productive Clinical Research Physician involved in the conduct of clinical research from protocol development through publication for a number of oncology indications from phase I to phase III. Dr Lacombe contributed to the strategic evolution of the EORTC pan-European clinical and translational research infrastructure by setting up various supportive assets such as regulatory and pharmacovigilance expertise as well as partnership models with the pharmaceutical industry. Dr Lacombe rose to the position of Director EORTC Headquarters in 2010, and in April 2015 was appointed EORTC Director General. In his current position, Denis Lacombe is now involved in the coordination and administration of all EORTC activities in order to promote the EORTC as a major European organization in Cancer Clinical and Translational Research and is responsible for the organization of scientific activities, public relations and strategies as defined by the EORTC Board as well as for internal and external communications.

Dr Lacombe is the author of well over 104 peer reviewed publications and communications that have had a positive impact on the future of cancer therapy.

Julian Isla

Julian Isla is the chairman of the European Dravet Syndrome Federation, an European organization of patients with Dravet Syndrome. Julian Isla founded Dravet Syndrome Foundation seven years ago and now it's the Director of Technology and Innovation. Dravet Syndrome Foundation is committed to find new treatment for Dravet Syndrome, an epileptic encephalopathy having long lasting seizures refractory to treatment as severe developmental delay as main symptoms. Julian is the father of Sergio, a young boy six years old who has Dravet Syndrome. Julian is software engineer by training and he works for Microsoft as full time employee. Despite of not having a neuroscience or medical background he gained the skills to be part of the Orphan Drug Committee at European Medicines Agency (EMA) as patient representative. Julian is also part of the Therapeutic Advisory Group for Eurordis, the biggest organization of rare diseases in Europe. In Spain he is ambassador of the Spanish Rare Diseases Federation and member of Ciberer (Spanish Network for research on rare diseases) scientific advisory group".

Ulrich Jäger

Ulrich Jäger is Professor of Haematology and Head of the Division of Haematology and Hemostaseology at the Medical University of Vienna. He was President of the European Haematology Association (EHA) from June 2011 to June 2013 and is currently a member of the European Biomed Alliance and the European Alliance for Personalised Medicine. He gained his professional experience at the Medical University of Vienna and at Washington University, St. Louis, Missouri. He is currently leading a haematology institute which focuses on translational research and precision medicine.

Dr Jäger's scientific interests are molecular haematology, molecular biology of leukaemias and lymphomas, minimal residual disease, molecular mechanisms of chromosomal translocations and chronic lymphocytic leukaemia. He is or was the leader of several international studies in lymphoma. His laboratory and department are cooperating with numerous institutions in Europe, the United States and Asia. He has received several scientific awards and has published a large number of original articles, review articles, and book chapters.