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Stakeholders and Communication Division

PCWP/HCPWP Session on communication and information on medicines 8 March 2016

Speakers' biographies

David Haerry

David Haerry is a patient representative of the European Aids Treatment Group (EATG) and current co-chair of the EMA Patients' and Consumers' Working Party (PCWP).

As a patients' rights activist, David has been active in a broad range of HIV/AIDS-related issues, including drug development, regulatory issues, biomedical prevention research, travel and residency restrictions for people with HIV/AIDS, risk communication and doctor/patient communication. He is also involved in a number of academic education projects.

Gonzalo Calvo

Gonzalo Calvo is currently 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).

Juan Garcia Burgos

Juan Garcia is Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as an urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 as Product Team Leader and responsible for the Secretariat of the Efficacy Working Party, involved in the preparation of clinical guidelines for drug development. He took up new responsibilities in 2005 by moving to the area of communication where he acted as Section Head for Public Information and Stakeholder Networking, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences.

In 2014 he was appointed Service Head for Medical and Health Information within the Stakeholders and Communication Division.

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Giulio Formoso

Giulio Formoso is a pharmacist/epidemiologist working for the Health and Social Policies Directorate of the Emilia-Romagna Region (Italy). His main responsibilities include: evidence-based assessment of new drugs within the Regional Drug Commission of the Emilia-Romagna Region and in collaboration with international organisations (WHO, EUnetHTA); design and coordination of epidemiological and record-linkage studies, surveys, systematic reviews and technology assessment reports; scientific writing and implementation of evidence-based information. He holds an MPH (from the Johns Hopkins University - USA) and a Master degree in Pharmacy (from the University of Rome – Italy).

Laurent Brassart

Laurent Brassart is principal scientific administrator at the EMA, responsible for information compliance and consistency. The main task of his position is to promote the translation of scientific assessment into adequate information on medicines according to stakeholders' expectations. Educated as medical doctor specialised in pain treatment and clinical trial methodology, he has a wide experience in scientific and regulatory supervision of medicines, from assessment to interaction with stakeholders. For example, he led the preparation of the Agency's report on patients', consumers' and healthcare professionals' expectations on information on benefit-risk of medicines.

Joan Peppard

Joan Peppard is Chief Pharmacist in Midland Regional Hospital Tullamore, Co Offaly and the President of the European Association of Hospital Pharmacists (EAHP) since June 2015. Joan previously held the post of Director of Professional Development for the EAHP and has twice been the head of the Hospital Pharmacists Association of Ireland in the position of President. Joan has a keen interest in the growth and development of hospital pharmacy and a strong commitment to excellence in patient care.

Dolores Montero Corominas

Dolores Montero, MD, PhD, is the Head of Pharmacoepidemiology and Pharmacovigilance at the Department of Medicines for Human Use from the Spanish Agency on Medicines and Healthcare Products, and has been working in this field for more than 20 years. She is a member of the Pharmacovigilance Risk Assessment Committee since its creation and was actively involved in the former Pharmacovigilance Working Party. She has participated in national and international research projects in the area and has a master degree in pharmacoeconomics.

Dominic Way

Dominic Way is a final year Ph.D. researcher specialising in risk communication and regulation at the King's Centre for Risk Management, King's College London. He completed a B.A. Geography degree (1st Class, Hons.) and M.Sc. in Risk Analysis (Distinction) at King's. He has published peer review articles (e.g. on transparency, pharmaceutical regulation, the social amplification of risk, and decision-making science) and lectured on risk regulation, management, communication and assessment to both public and private institutions at international conferences, workshops and other events (e.g. at the US FDA, Health Canada and various EU national competent authorities). For the past five years, his primary doctorate research has centred on empirically measuring and evaluating the effects of pharmaceutical transparency policies on building trust in institutions and confidence in decision-

makers. Dominic recently finished lecturing as a visiting research fellow at Maastricht University, has organised high-level international workshops on risk regulation in both the US and Europe and is an active member of the Society for Risk Analysis (SRA): treasurer/secretary for the Risk, Policy and Law (RP&L) speciality group (2013-2016).

Frederic Bouder

Frederic Bouder is currently Assistant Professor in the Department of Technology and Society Studies at Maastricht University. Throughout his academic career, at both Maastricht University as well as King's College London, he has developed policy oriented research on risk communication and risk regulation, with a strong transatlantic and comparative dimension. His research has particularly focused on the critical policy aspects of the acceptability and tolerability of risks. He has worked extensively on pharmaceutical issues (drugs, vaccines, biotechnologies, genetic risk), occupational safety, chemical, nuclear risks, regulatory governance and sustainable development. Frederic has given numerous talks to North American and European regulators most notably FDA, OMB and EMA. Prior to obtaining his doctoral degree as King's College London Frederic was active as an administrator in the Public Governance and Territorial Development Directorate of the Organization for Economic Co-operation and Development (OECD). In 2007-2009 he advised the UK Sustainable Development Commission on economics and policy as well as the UK Department for Business Innovation and Skills (BIS) on Risk Communication. In 2008 he co-led a review of the UK Health and Safety Executive's Risk Communication. In 2009-2010 he was seconded to the European Medicines Agency as National Expert. Since 2013 he has advised the Dutch Ministry of Infrastructure and the Environment (IenM).

Martin Dorazil

Martin Dorazil works since 2014 as a legal officer in the European Commission's Directorate-General for Health and Food Safety on issues related to medicinal products' marketing authorisations. Prior to that he worked in other departments of the European Commission namely on issues related to the Pharmaceutical Sector Inquiry and antitrust cases concerning medicinal products (DG Competition, 2009-2014) and on issues related to patients' rights in cross-border healthcare (DG SANCO, 2005-2009). Before joining the European Commission he worked at the ministry of home affairs of the Czech Republic. He is a lawyer by training.

Sara Rubinelli

Sara Rubinelli holds a degree in Classics and Philosophy from the Catholic University of Milan (I) and a PhD from the University of Leeds (UK) in the areas of argumentation theory, persuasion and rhetoric. From 2005 to 2009 she was the Scientific Coordinator of the Institute of Communication and Health of the University of Lugano (CH). Since September 2009 she is Scientific Coordinator of the Human Functioning Unit at Swiss Paraplegic Research (CH) and leads there the Person-Centered Healthcare Group. Since September 2012 she is Assistant Professor in Health Sciences with a focus in health communication at the Department of Health Sciences and Health Policy of the University of Lucerne (CH). She is the Chair of pEACH, the research implementation committee of the European Association for Communication in Healthcare (EACH).