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Patients and Healthcare Professionals Department

# Speakers' biographies

## Dr Michel Delvaux

Dr Michel Delvaux is a specialist in gastroentrerology and has a PhD in molecular pharmacology.

Dr Delvaux is Associate Professor of Medicine and Gastroenterology at the University Hospital of Strasbourg in France. He is currently the representative of the United European Gastroenterology in the HCPWP.

## Mr 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.

## Dr Pekka Kurki

Dr. Pekka Kurki, M.D, Ph.D, acts as a research professor at the Finnish Medicines Agency (Fimea).

Before joining the Finnish regulatory agency in 1997, he worked in the pharmaceutical industry (clinical research), both in Europe and in the U.S.A. Dr. Kurki's clinical speciality is internal medicine with sub-speciality in rheumatology. He has a teaching affiliation to the University of Helsinki (clinical immunology). His scientific interest also includes cell biology, rheumatology and regulatory science. He has had several scientific positions at the European Medicines Agency (EMA), including the membership the Committee of Human Medicinal Products (CHMP, 2000-7), chairmanships of the working parties for comparability (2002-3), biosimilars (BMWP, 2004-7), cell therapy (2002-4), and cell-based medicinal products (CPWP 2005-7). In addition, he acted as the chair of the ad hoc group for xenogeneic cell therapy (2001-3), a member of the biologicals working party (BWP, 1998-9) and a member of the ad hoc innovation Think Tank group of EMA (2005-7).

Currently, he is an alternate member of the EMA management board and an expert in the CHMP biosimilar working party (BMWP).

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# Dr Christian K. Schneider

Christian K. Schneider, MD, is Medical Head of Division Medicines Licensing and Availability at the Danish Medicines Authority. Between 2009 and 2013 he was chairman of the European Medicines Agency's (EMA) Committee for Advanced Therapies (CAT). Between 2007 and 2011 he was co-opted member of the CHMP, the Committee for Medicinal Products for Human Use, for the area of "Quality and safety (biological), with expertise in Advanced Therapies - Gene, Cell and Tissue Therapies" and at present he is the Danish Alternate member of CHMP. He is chairman of the CHMP Working Party on Similar Biological Medicinal Products (BMWP) and was previously member of the CHMP Scientific Advice Working Party (SAWP). He has been actively involved in the drafting of several multidisciplinary CHMP guidelines. Before joining the Danish Health and Medicines Authority as a Senior Medical Officer in 2011, he was Director and Professor and Head of Division "EU Co-operation/Microbiology" at the Paul-Ehrlich-Institut, the German Federal Agency for Sera and Vaccines. Before, Christian K. Schneider was working for more than two years as a postdoctoral researcher at the Max-Planck-Institute for Neurobiology, Neuroimmunology (Martinsried, Germany), where he worked in experimental immunology in the field of T cell immunology of inflammatory myopathies and multiple sclerosis. During his clinical career, Christian K. Schneider worked in clinical immunology and hemato-oncology (Department of Internal Medicine III, University Erlangen-Nuremberg, Germany).

# Dr Martina Weise

Martina Weise, MD, works at the Federal Institute for Drugs and Medical Devices (BfArM), Germany, since 2001, where she is currently Head of the Unit on Diabetes/Cardiovascular System. She is also the alternate German member of the European Committee for Medicinal products for Human Use (CHMP) and Vice Chair of the Biosimilar Medicinal Working Party (BMWP). She has extensive experience in drafting biosimilarity guidelines for the EMA and the WHO and, with her team, reviews biosimilar applications in the EU.

Dr. Weise is board-certified pediatrician, has over 10 years of professional experience in pediatrics including pediatric endocrinology and clinical and laboratory research in Germany and the USA. She has also published various scientific articles in international peer-reviewed journals focused on growth and adrenal disorders and, more recently, on biosimilars.

# Dr Robin Thorpe

Robin Thorpe PhD, FRCPath, was Head of the Biotherapeutics Group at the National Institute for Biological Standards and Control (NIBSC) which is part of the Medicines and Healthcare Products Regulatory Agency until he retired from NIBSC in October 2013. He was previously Head of the Division of Immunology & Endocrinology from 2004-2006 & Head of the Division of Immunobiology from 1986-2004. Since joining NIBSC in 1980 he has worked on cytokines, monoclonal antibodies, immunoglobulins and the immunology of infectious agents. Recent interests include the unwanted immunogenicity of biologicals, biosimilars, development of improved bioassays for cytokines, the immunology of monoclonal antibodies, cytokine contamination of biological products and cytokine involvement in adverse reactions to biologicals. He is a Fellow of the Royal College of Pathologists.

Dr Thorpe attends meetings of the Biologicals Working Party & Biosimilars Working Party of the CHMP at the EMEA. He has been a member of the Biologicals sub-committee of the CSM and a member of the External Advisory Panel to the CSM. He is a member of the British Pharmacopoeia Commission (MHRA) Expert Advisory Group NOM, the British Pharmacopoeia Panel of Experts on Biological and

Biotechnological Products and chairman of the Working Group on Monoclonal Antibodies of the European Pharmacopoeia. He was a member of the Biologicals & Vaccines Expert Advisory Group of the CHM. He is a biologicals advisor to the WHO INN programme. He is the Chairman of the IUIS Standardisation Subcommittee for chemokines and the standardisation and nomenclature committee of the International Cytokine Society.

Dr Thorpe has over 240 publications in scientific journals and books. He is an associate editor for the journal Cytokine, Editor-in- Chief for Biologicals, Deputy Editor-in-Chief for GaBi Journal and editorial board member of the Journal of Immunological Methods & Current Analytical Chemistry.

# Dr T.J. (Thijs) Giezen

Thijs Giezen (1982) studied pharmacy at Utrecht University and obtained his PharmD in December 2006. He subsequently completed a PhD aimed at characterising the safety profile of biopharmaceuticals in the post-marketing setting and opportunities to minimise the risk for the patient. His PhD was combined with a position as a pharmacovigilance assessor at the Medicines Evaluation Board. During his PhD he obtained a MSc degree in epidemiology. After his PhD, Thijs was trained as a hospital pharmacist at the Medical Spectrum Twente, Enschede. From March 2014 onwards Thijs works as a registered hospital pharmacist at the Foundation Pharmacy for Hospitals in Haarlem, (Netherlands). Thijs also holds a position as an external assessor at the Medicines Evaluation Board in Utrecht.

He is a member of the EMA Working Party on Biosimilar Medicinal Products (BMWP) of the CHMP.

# Dr 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).

# Ms Alison Lightbourne

Alison is a Policy Manager at IAPO (the International Alliance of Patients Organizations), a unique global alliance representing patients of all nationalities across all disease areas and promoting patient-centred healthcare around the world. She manages and coordinates IAPO's policy activities including policy development, communication and projects, engaging member organisations and representing their interests and needs when advocating at the global level and regional level on key issues affecting patients.

# Ms Clare Jacklin

Clare joined National Rheumatoid Arthritis Society as the Volunteer Network Manager in June 2007 and now holds the position of Director of External Affair on the senior management team.

NRAS (National Rheumatoid Arthritis Society) is the only UK charity focussing specifically on supporting those living with rheumatoid disease.

Clare has managed the rapid growth of NRAS patient groups across the UK as well as extending the role of RA patients participating in a wide variety of projects including clinical and social research. Key projects which Clare has managed in recent years include

- a programme of regional workshops on the topic of impact of RA on work and employment
- a unique study into the impact of RA on the family of those with the disease
- a major research study into the impact of RA on Emotions, Relationships and Sexuality
- coordinating a stakeholder event hosted by NRAS on the topic of emerging biosimilar medicines
- development and establishment of volunteer peer to peer training programme

A key member of the senior management team of NRAS, Clare is committed to developing the society to ensure that the support that people with Rheumatoid Arthritis need continues to be provided and that the patient voice of people living with RA is heard loud and clear.

# Ms Hilda Juhász

Hilda is a Policy Officer in charge of biotechnology and healthcare industries (Directorate Resources Based, Manufacturing and Consumer Goods Industries) of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs at the European Commission. She has been co-ordinating the activities of the Working Group "Access to and uptake of biosimilar medicinal products" in the framework of the Commission's "Process on Corporate Responsibility in the Field of Pharmaceuticals" which was launched end of 2010.

Her background is in economy and political sciences, graduated at the Ludwig-Maximilians-Universität in Munich/Germany. Before she joined the Commission she worked as an Investor Relations professional with focus on biotech financing.