19 July 2016
EMA/497761/2016
Inspections and Human Medicines Pharmacovigilance Division

List of participants

10th Stakeholder Forum on the Pharmacovigilance legislation

21 September 2015, 09.00-13.00, Room 3/E

Speakers	Institution / Company
Guido Rasi	European Medicines Agency (EMA)
June Raine	Medicines and Healthcare Products Regulatory Agency (MHRA), UK
Fergus Sweeney	European Medicines Agency (EMA)
Helen Lee	European Commission (EC)
Peter Arlett	European Medicines Agency (EMA)
Almath Spooner	Health Products Regulatory Authority (HPRA), IE
Xavier Kurz	European Medicines Agency (EMA)
Philip Tregunno	Medicines and Healthcare Products Regulatory Agency (MHRA), UK
Spiros Vamvakas	European Medicines Agency (EMA)
Alison Cave	European Medicines Agency (EMA)
Jamie Wilkinson	Pharmaceutical Group of the European Union (PGEU)

Member States	Institution / Company
Giuseppe Pimpinella	Italian Medicines Agency (AIFA) (virtual meeting)
Ilaria Baldelli	Italian Medicines Agency (AIFA) (virtual meeting)
Elena Marotta	Italian Medicines Agency (AIFA) (virtual meeting)
Suvi Loikkanen	Finnish Medicines Agency (virtual meeting)
Roxana Stroe	National Agency for Medicines and Medical Devices, RO (virtual meeting)
Virginie Bacquet	French National Agency for Medicines and Health Products Safety, FR
Peter Bachmann	Federal Institute for Drugs and Medical Devices, DE
Margarida Guimaraes	National Authority of Medicines and Health Products, I.P., PT

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EMA	
Georgy Genov	European Medicines Agency (EMA)
Marie-Helene Pinheiro	European Medicines Agency (EMA)
Juan Garcia	European Medicines Agency (EMA)

Patient / Health Care Professional	Institution / Company
Andres Suarez	Spanish Agency of Medicines and Medical Devices (AEMPS)
Erzsebet Podmaniczky	Standing Committee of European Doctors (CPME)
Donald Singer (Session 1 panellist)	European Association for Clinical Pharmacology and Therapeutics (EACPT)
Raymond Anderson	Pharmaceutical Group of the European Union (PGEU)
Ber Oomen	The European Specialists Nurses Organisations (ESNO)
Roberto Frontini (Session 3 panellist)	European Association of Hospital Pharmacists (EAHP)
Tibor Hlavaty	United European Gastroenterology (UEG)
Barbro Westerholm	AGE Platform Europe (AGE)
Rafal Swierzewski (Session 2 panellist)	European Cancer Patient Coalition (ECPC)
Cathalijne van Doorne	European Federation of Neurogical Associations (EFNA)
Hildrun Sundseth (Session 3 panellist)	European Institute of Women's Health (EIWH)
Christoph Thalheim (Session 3 panellist)	European Multiple Sclerosis Platform (EMSP)
Albert van der Zeijden (Session 1 panellist)	International Alliance of Patients' Organizations (IAPO)
Francois Houyez (Session 2 panellist)	European Organisation for Rare Diseases (Eurordis)
Francesca Cattarin (Session 1 panellist)	The European Consumers' Organisation (BEUC)
Walter Marrocco	Italian Federation of Italian General Practitioner
Kaisa Immonen-Charalambous	European Patients Forum (EPF)
Viorica Cursaru	Myeloma Euronet Romania
Ferdinand Breedveld	European League Against Rheumatism

Industry	Institution / Company
Catherine Akers (Session 1 panellist)	Amgen, representing EBE
Zoe Conway (Session 2 panellist)	Roche, representing EBE
Katrina Skeer	Representing EBE
Veronique Debaut	Representing EBE
John Poland	Representing ACRO
Dairine Dempsey	ICON, representing ACRO
Drew Kilpatrick (Session 3 panellist)	Chiltern, representing ACRO
Fiona Hurrell	PPD, representing ACRO
David Hillman	PPD, representing ACRO
Stefan Kaehler (Session 2 panellist)	Celgene, representing EUCOPE
Panos Tsitsios	VIANEX S.A, representing EUCOPE
John Poustie	Norgine, representing EUCOPE
Boris Thurisch	BPI, representing EUCOPE
Philippe Bertrand	Onxeo, representing EUCOPE
Maren v Fritschen	EUCOPE

Barbara Morollo	Representing EUCOPE
Françoise Dumas Sillan	Pfizer, representing Vaccines Europe
Marc Ceuppens	Janssen, representing Vaccines Europe
Miranda Moussa (Session 1 panellist)	AESGP
Maria Spyt (Session 2 panellist)	Johnson & Johnson, representing AESGP
Barbara De Bernardi	Pfizer, representing AESGP
Sylvie Rabut	Urgo, representing AESGP
Amal Benkritly	Sanofi, representing AESGP
Yasmine Boulkroun	Representing AESGP
John Barber (Session 1 panellist)	Dr. Reddy's Laboratories, representing Medicines for Europe
Michael Forstner (Session 2 panellist)	Acino Pharma, representing Medicines for Europe
Tanja Peters	Boehringer Ingelheim, representing Medicines for Europe
Uwe Gudat	Merck, representing Medicines for Europe
Katarina Nedog	Medicines for Europe
Vishal Manjibhai Ghori	Billev Pharma East, representing Medicines for Europe
Telma Costa	Representing Europharm SMC
Margarida Estudante	Representing Europharm SMC
Esteban Herrero-Martinez	Abbvie, representing EuropaBio
Johan Hellmer	Shire, representing EuropaBio
Margaret Walters	Merck, representing EuropaBio
Merete Schmiegelow	Novo Nordisk, representing EuropaBio
Milena Vakrilova	Novartis, representing EuropaBio
Pedro Franco	Merck Sereno, representing EuropaBio
Sam Temple-Scotton	SFL, representing EuropaBio
Simon Bennett	Biogen , representing EuropaBio
Christine Abouzeid	Representing EuropaBio
Vicki Edwards (Session 1 panellist)	Abbvie, representing EFPIA
Guy Demol	MSD, representing EFPIA
Dave Lewis	Novartis, representing EFPIA
Sue Rees (Session 3 panellist)	Amgen, representing EFPIA
Yogen Logesvaran	Jansen/J&J, representing EFPIA
Sarah Montagne	Bayer, representing EFPIA
Pari Nasseri-Sina	GSK, representing EFPIA
Jean Kilgour-Christie	Takeda, representing EFPIA

Programme Committee

Guido Rasi - European Medicines Agency (EMA)

Professor Guido Rasi began his second term as Executive Director of EMA on 16 November 2015.
From November 2014 to mid-November 2015, Professor Guido Rasi served as EMA's Principal Adviser in Charge of Strategy.
From November 2011 to November 2014 he was the Executive Director of the European Medicines Agency and a member of its Management Board in the three years prior to this.
He was Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008.
He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008.
From 2005 to 2008 he was Director of the Institute of Molecular Medicine of the National Research Council in Rome.
From 1990 to 2005 Professor Rasi worked at the Institute for Experimental Medicine of the National Research Council, Italy.
He had a teaching and research experience at the University of California, Berkeley in 1999.
Professor Rasi holds a degree in medicine and surgery, with specialisations in internal medicine, allergology and clinical immunology, from the University of Rome.
From 1978 to 1990, he worked as a physician in hospital, research and private practice. He is author of more than 100 scientific publications.
Prof Rasi was born in Padova, Italy and is married with two children.

June Raine - Medicines and Healthcare Products Regulatory Agency (MHRA), UK

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.

Fergus Sweeney - European Medicines Agency (EMA)

Fergus Sweeney is Head of Inspections, Human Medicines Pharmacovigilance & Committees Division at the European Medicines Agency.
Brief Employment History
In 1999 Fergus joined the Agency Inspections Sector to coordinate GCP and more recently Pharmacovigilance inspections. He was appointed Head of Sector, Compliance and Inspections in May 2009 and as Head of Division Inspections and Human Pharmacovigilance in August 2013.
Fergus has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Prior to joining the Agency he worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance.

Helen Lee – European Commission

Helen Lee is an administrator in the European Commission working in Unit B5 - Medicines: policy, authorisation and monitoring of Directorate General for Health and Food Safety. She joined the unit dealing with the pharmaceutical legislation and the European Medicines Agency in 2012 prior to which she had worked on food related issues in the European Commission and the UK administration.

Peter Arlett - European Medicines Agency (EMA)

Education:

- Qualified in Medicine from University College London (UCL) (1991).
- Member of the Royal College of Physicians (MRCP) of London (1994).
- Member of the Faculty of Pharmaceutical Medicine (MFPM) of the Royal College of Physicians of London (2002).
- Fellow of the Faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London (2007).
- Managing Successful Programmes (MSP) Practitioner (2014)

Career to date:

- Head of Pharmacovigilance and Epidemiology Department, EMA (September 2016 – present)
- Head of Pharmacovigilance Department, EMA (August 2013 – August 2016)
- Head of Pharmacovigilance and Risk Management Sector, EMA (2008-2013)
- Principal Administrator, Pharmaceuticals Unit, DG Enterprise and Industry, European Commission (2003-2008).
- UK delegate to the European Committee for Human Medicinal Products (CHMP) (2001-2003).
- Specialist Assessor and Manager, Medicines Control Agency (now MHRA) (1996-2001).
- Hospital Physician, UK NHS, UCL, Oxford, Hammersmith (to 1996)

Almath Spooner - Health Products Regulatory Authority (HPRA), IE

Almath Spooner is currently the Pharmacovigilance and Risk Management Lead at the Health Products Regulatory Authority (HPRA) and Vice Chair of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). Since joining the Irish Medicines Board in 2007, Almath has contributed to the development of EU benefit-risk monitoring systems for medicines initially as part of the CHMP's Pharmacovigilance Working Party and subsequently at the PRAC. Almath is a member of the Heads of Medicines Agencies' European Risk Management Strategy Facilitation Group, the EMA's Incident Review Network and has represented the EU at ICH. Dr. Spooner is a pharmacist by training with a PhD from Trinity College Dublin and additional postgraduate qualifications in statistics, pharmaceutical medicine and law. Prior to joining the IMB, Almath had experience in clinical and academic pharmacy.

Xavier Kurz - European Medicines Agency (EMA)

Xavier Kurz graduated in 1982 as a Medical Doctor at the University of Liege, Belgium. He specialised in Tropical Medicine and worked for several years in public health projects in Africa and Asia. He obtained a MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He joined the Department of Pharmacology of the University of Liege, where he developed and conducted pharmacoepidemiological and pharmacoeconomic studies on vascular disorders and dementia. He joined the Belgian Centre for Pharmacovigilance (Ministry of Health) in 1995 and the European Medicines Agency in 2005. He is Head of the Surveillance & Epidemiology (SVE) Service in the Pharmacovigilance and Epidemiology Department.

Philip Tregunno - Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Phil is the Signal Management Unit Manager within MHRA's Vigilance Intelligence and Research Group (VIRG) and has over thirteen years of experience working in pharmacovigilance. For the past eight years he has been responsible for leading and developing the Signal Management function, including systems, processes, and relevant aspects of Pharmacovigilance Legislation. He led the development of the MHRA's proposal to lead the EU Innovative Medicines Initiative WEB-RADR project and subsequently coordinated the formation of the public consortium and its integration with the EFPIA consortium. Phil is now the Managing Entity and Work Package 5 lead for the project.

Spiros Vamvakas - European Medicines Agency (EMA)

Career to date:

- Head of Scientific Advice, European Medicines Agency (2009-present)
- Deputy Head of Product Development Scientific Support, European Medicines Agency (2015-present)
- Deputy Head of Scientific Advice and Orphan Drugs (ad interim), European Medicines Agency (2004-2009)
- Principal Scientific Administrator, European Medicines Agency (1999-2004)
- Associate Professor, University of Würzburg, Germany (1999-present)
- Privat Dozent, University of Würzburg, Germany (1993-1999)
- Lecturer, University of Würzburg, Germany (1990-1993)
- Post-doctoral Fellow, University of Rochester Medical Center, United States (1988-1990)
- Assistant, University of Wurzburg, Germany (1984-1988)

Education:

- Board-certified physician for pharmacology and toxicology, Bavarian Chamber of Physicians, Munich, Germany (1994)
- Habilitation for pharmacology and toxicology, University of Würzburg, Germany (1993)
- Medical degree, University of Wurzburg, Germany (1984)

Alison Cave - European Medicines Agency (EMA)

Education:

- BA Honours degree in Physiology - King's College London, University of London
- PhD in Biochemistry -St. Thomas' Hospital London, University of London

Career to date:

- 01-2016 – current: Principal Scientific Administrator, Pharmacovigilance and Epidemiology Department, EMA
- 05-2013 -12-2015: Head of Cellular, Developmental and Physiological Sciences, The Wellcome Trust, London
- 10-2010 –04-2013: Expert Scientific Assessor, MHRA, London.
- 10-2008 –10-2010: Senior Scientific Assessor, MHRA, London.
- 09-2006 - 09-2008: Non Clinical Senior Lecturer, King's College London
- 09-1998 – 09-2006: Non Clinical Lecturer, King's College London
- 07-1997 – 09-1998: Scientific Assessor, Medicines Control Agency, London SW8 5NQ
- 04-1994 – 07-1997: Post-doctoral Fellow, Department of Radiological Sciences, Guy's Hospital, London
- 03-1992 – 04-1994: American Heart Association Research Fellow, University of Boston Medical School, Boston, USA.

Jamie Wilkinson - Pharmaceutical Group of the European Union (PGEU)

Mr Wilkinson commenced his role as Pharmaceuticals and Professional Affairs Adviser of the PGEU in January 2014 before becoming Director of Professional Affairs in April 2015. The Pharmaceutical Group of the European Union (PGEU) is the European Association representing community pharmacists in 32 European countries. A pharmacist by training, he has practice experience in community pharmacy in the UK across the sector and also has experience as a pharmacy practice Teacher Practitioner at the Reading School of Pharmacy. He is a British national, was educated at the Universities of Kingston & St Georges London, holds an MSc in Social Research Methods from the University of Sussex and is currently working towards a Masters in Public Health at the University of Sheffield. Mr Wilkinson is a member of the Royal Pharmaceutical Society UK and a fellow of the Royal Society for Public Health UK.

Session 1 Panellists

June Raine - Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Fergus Sweeney – European Medicines Agency (EMA)

Helen Lee - European Commission (EC)

Peter Arlett – European Medicines Agency (EMA)

Almath Spooner - Health Products Regulatory Authority (HPRA), IE

Francesca Cattarin - The European Consumers' Organisation (BEUC)

Francesca Cattarin joined the European Consumer Organization (BEUC) in February 2016. As Health Policy Officer she provides BEUC and its members information and advice on access to medicines policies. She is a member of the European Medicines Agency patients and consumers working party and represents BEUC at EU health policy platform and in other fora. She previously worked for the Health Italian Ministry as Policy Advisor for the "Progetto Mattone Internazionale", after an internship at the European Social Observatory (ESO) where she investigated the Directive on the application of patients 'rights in cross-border healthcare. Francesca graduated in European studies at Cesare Alfieri University in Florence.

Albert van der Zeijden - International Alliance of Patients' Organizations (IAPO)

Patient advocate since 1980 and a chronic patient himself.
Former Co-founder and chairman of patients organisations on the local, national, European and international level, including the EMA eligible organisation International Alliance of Patients' Organizations.
Currently amongst other commitments committee member (alternate) of the PRAC and member of the board of Lareb.

Donald Singer - European Association for Clinical Pharmacology and Therapeutics (EACPT)

Catherine Akers - Representing European Biopharmaceutical Enterprises (EBE)

Work experience:

- May 2011 – Present Global Regulatory and R&D Policy, Amgen Ltd, Sr Manager
  - Biosimilar Policy including an interest in pharmacovigilance requirements for biologics including biosimilars, as called out in the recent update to the EU Pharmacovigilance legislation, together with the need to ensure traceability of biologics from prescription to end-user, in addition to other issues which effect biologics and biosimilars.
  - involved wtih the European Trade associations at both EBE and EuropaBio.
- September 2006 - April 2011 - Regulatory Affairs, Amgen Ltd
  -International Regulatory Affairs Representative within the Oncology TA.
  -To provide guidance to the GRT with regard to International guidance and requirements.
  -Support developmental and commercial products within the International region.
  September 2004 – September 2006 - Regulatory Affairs, Amgen Ltd
  -Supporting Life Cycle Management team with special regard to CMC activities
  Supporting clinical trial activities
- April 2003 – September 2004 - Regulatory Affair, Amgen Ltd
  -Supporting New Territories and Trans Licensing team, to ensure timely submission and approval of variations and new MAAs in these regions.

Miranda Moussa - Representing AESGP

Miranda Moussa is the Manager for Safety Issues and Medical Devices at AESGP. In this role, she manages the newly-created AESGP pharmacovigilance committee and coordinates the policy of AESGP in the area of pharmacovigilance. She also helped defining the AESGP

policy position on the proposed regulation on fees payable to the EMA for the conduct of pharmacovigilance activities.
Before joining AESGP in 2012, she worked at the European Commission (Medical Devices Unit) and supported regulatory activities of pharmaceutical companies in Eastern European, Asian and African countries.
Miranda is a Doctor of Pharmacy specialized in regulatory affairs with a Master of Science program in international drug development and registration, earned respectively at the Universities of Rouen and Paris XI. "

Vicki Edwards - Representing EFPIA

John Barber - Representing Medicines for Europe

QPPV and Director – Head of Pharmacovigilance European Operations, Dr. Reddy's Laboratories

- Approximately 25 years in the pharmaceutical industry, of which the last 10 have been in pharmacovigilance.
- QPPV at Dr Reddy's since 2010
- Global Clinical Pharmacovigilance Manager at Glenmark Pharmaceuticals 2008-2010
- Director of Scientific Affairs at Alliance Pharmaceuticals 2000 to 2008
- Prior roles were with ICI Pharmaceuticals, Glaxo Wellcome, Roche and PharmaVentures
- Current member of the Medicines for Europe Pharmacovigilance Working Group leading the RMP work stream
- Lead on pharmacovigilance for the Britsh Generic Manufacturers Association (BGMA)
- Past President of the UK Pharmaceutical Information and Pharmacovigilance Association (PIPA) 2005-2009

Session 2 Panellists

June Raine - Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Peter Arlett – European Medicines Agency (EMA)

Xavier Kurz – European Medicines Agency (EMA)

Philip Tregunno - Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Rafal Swierzewski - European Cancer Patient Coalition (ECPC)

Francois Houyez - European Organisation for Rare Diseases (Eurordis)
Director of Treatment Information Access at Eurordis.
Advisor to the SCOPE joint action on pharmacovigilance.
Participant in the Web-RADR project.
Member of the EMA Patients' and Consumers' Working Party.

Zoe Conway - Representing European Biopharmaceutical Enterprises (EBE)
Zoe is a medically qualified UK national, who worked in the NHS in general medicine and paediatrics for a number of years before joining the pharmaceutical industry as a Clinical Research Physician. She has over 20 years of industry experience in both UK affiliate and Headquarter roles, initially in clinical development and more recently in pharmacovigilance. Throughout her industry career, Zoe has been interested in compliance and quality related issues with experience in the implementation of the EU Clinical Trial Directive, introduction of a company Quality Management System and leadership of a central support group with responsibility for compliance, learning and development, continuous improvement and resource and capacity planning.

Maria Spyt - Representing AESGP

Stefan Kaehler - Representing EUCOPE
Stefan Kähler is EEA- QPPV & Executive Director Global Drug Safety and Risk Management at Celgene. Within the more than 15 years experience in the pharmaceutical industry he has held positions of increasing seniority with responsibility for Europe as well as for the World within drug development, regulatory affairs, toxicology, clinical research and development, drug safety and risk management, including serving as QP batch release and Qualified Person for Pharmacovigilance (QPPV). Since many years he is elected Chairman for Clinical Research of the Austrian Pharma Associations (Pharmig) and represented EUCOPE at the EMA industry stakeholder meetings multiple times. He is the author of several scientific publications, including papers on Pharmacovigilance, in peer-reviewed scientific journals.
Before joining the pharmaceutical industry in 1999, he worked at the Leopold-Franzens University of Innsbruck for more than 10 years in the area of clinical and experimental pharmacology and toxicology and he lectures in several disciplines of pharmacology & toxicology there until today.
Stefan is Professor (venia docendi) in pharmacology & toxicology and has a Doctor of natural sciences and a Magister in Pharmacy.

Michael Forstner - Representing Medicines for Europe
Dr. Michael Forstner is Global Head of Pharmacovigilance at Acino Pharma in Switzerland where his key responsibilities are the creation and maintenance of a compliant global PV system. Michael is also in the planning, development, implementation and evaluation of (benefit-)risk management solutions, as well as the optimization of processes around benefit-risk management. He is developing and applying (benefit-) risk analysis

methodologies in order to make RM planning more formally reproducible. Furthermore, he supports the development and implementation of additional risk minimization and PV measures in the context of RMPs, and is involved in teaching and training activities on pharmacovigilance and pharmacoepidemiology at various European institutions.

Session 3 Panellists

Almath Spooner - Health Products Regulatory Authority (HPRA), IE

Peter Arlett – European Medicines Agency (EMA)

Spiros Vamvakas - European Medicines Agency (EMA)

Alison Cave - European Medicines Agency (EMA)

Jamie Wilkinson - Pharmaceutical Group of the European Union (PGEU)

Roberto Frontini - European Association of Hospital Pharmacists (EAHP)

Roberto Frontini studied Pharmacy at the University of Hamburg from 1988 to 1992 and was post graduate student in pharmaceutical technology at the same University till 1992. 1993 he obtained the PhD (Dr.rer.nat.) and worked at the hospital of the University of Lübeck until 1995. 1996 he obtained specialisation degree in Hospital Pharmacy and become 1996 head of the Pharmacy of the St.Franziskus-Hospital in Cologne. Since 2001 he is Director of Pharmacy at the University Hospital of Leipzig. He is since 2011 Qualified Person of the production Unit for Investigational Medicinal Products of the same pharmacy. He was trainer for pharmaceutical technology at the Chamber of Pharmacy Hannover between 1994 and 2005 and since 2004 he is holding the lecture on pharmacoepidemiology and Economics at the University of Leipzig, school of Pharmacy. Since 2015 he is Director of Practice at the Centre for Patient Safety in Leipzig. 2005 he was elected as Director of Finances of the European Association of Hospital Pharmacists (EAHP) and from 2009 to 2015 he was its president.

His special fields of interest are pharmacoepidemiology and patient safety. He was author and co-author of numerous publications and in 2014 he was nominated director of the new Centre for Patient Safety at the University Hospital of Leipzig.

Christoph Thalheim - European Multiple Sclerosis Platform (EMSP)

Born in 1952 in Dresden, Germany, Christoph Thalheim spent the first part of his professional life in the German Air Force, where he got his university degree in pedagogics and left as Captain after 12 years of service. A complete new orientation towards the field of "Intercultural Learning" followed, caused by a sabbatical year, which saw him travelling once around the world.

Returned from this life-turning experience, Mr.Thalheim was called to Brussels to set up and run for 10 years the EU- liaison office of a major international NGO focussing on intercultural learning and international youth exchange programmes.

In the beginning of 2000, the third new professional challenge in his life came up as EU affairs consultant, working mainly as Secretary General of the European Multiple Sclerosis Platform (EMSP), the European Patient Advocacy Group representing the interests of meanwhile 38 national MS Societies and more than 600.000 people affected by MS.

In early 2012, Mr. Thalheim accepted the new position as (part time) Director External Affairs and Deputy CEO within EMSP. This, in parallel, allowed the space for a regular consultancy task in Public Affairs with RIMS, the European network for MS healthcare professionals with a specific focus on research and practice of rehabilitation.

Hildrun Sundseth – European Institute of Women's Health (EIWH)

President, European Institute of Women's Health, current. Board Member, European Institute of Women's Health. Former Head of EU policy, European Cancer Patient Coalition As long-standing Board member and - since December 2013 - President of the European Institute of Women's Health, Hildrun volunteers her support to guide the Institute's policy, strategy and communication to make gender equity in public health, bio-medical research, treatment and care a priority for EU action. Hildrun oversees the research and editing of the EIWH Policy briefs on various chronic diseases and how they differ in women and men, including prevention of major chronic diseases, vaccination and more recently safe medicines use during pregnancy.

Drew Kilpatrick - Representing ACRO

Drew has over 36 years pre-clinical/clinical research experience gained in both Pharma and the CRO industry covering efficacy and safety of drugs in development and for Marketed Products. Global responsibility for sponsor outsourced Pharmacovigilance activities for the past thirteen years in addition to leading a worldwide Pharmacovigilance department for 5 years. Experience in drug Pharmacovigilance recently expanded to cover devices. Named as one of the notable people in R&D by R&D Directions.

Sue Rees - Representing EFPIA

Sue has been in the pharmaceutical industry for over 25 years. Sue joined Amgen in 2013 as EU QPPV, based in the Cambridge office. Sue works closely with the Global Patient Safety team and a network of local safety officers to provide oversight of patient safety across the EU.

Sue is an honorary Fellow of PIPA (Pharmaceutical Information and Pharmacovigilance Association) and sits on the Efpia Pharmacovigilance Committee.

Prior to joining Amgen Sue spent 3 years at Eisai Europe Ltd as Head of International Pharmacovigilance and EU QPPV having previously held various roles in safety, medical information and marketing for GlaxoSmithKline and AstraZeneca operating at both the affiliate and global level. Sue holds a BSc (Hons) in Biochemistry and MSc in Immunology.