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Speaker biographies

Workshop on parallel scientific advice in drug development, 26 November 2013

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Guido Rasi

Professor Guido Rasi has been Executive Director of the European Medicines Agency since November 2011, and was a member of its Management Board in the three years prior to this. He was also Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008.

From 1990 to 2008 Professor Rasi worked in research at the Institute for Experimental Medicine of the National Research Council in Rome. He had a teaching and research experience at the University of California, Berkeley in 1999. He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008.

Professor Rasi holds a degree in medicine and surgery, with specialisation 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.

Tomas Salmonson

Tomas Salmonson, M.Sc., PhD, brings outstanding experience and expertise from a long career in the regulation of medicines both on a national and European level to his new role. A pharmacist by training, he is currently senior scientific advisor at the Swedish Medical Products Agency (MPA) in Uppsala, Sweden. He has been a member of the CHMP for more than 12 years. In 2012, Dr Salmonson was elected chair of the Committee for Medicinal Products for Human Use (CHMP); he was Vice chair of the CHMP from 2007 till 2012. He is also chair of the EMA Pharmacokinetics Working Party, and represents the EU at the ICH Steering Committee since 2007.

Ron L. Akehurst

Ron Akehurst is Professor Emeritus of Health Economics in the School of Health and Related Research (ScHARR), one of the world's leading centre for health services research, at the University of Sheffield, Sheffield, UK. Ron set up the School in 1993 and served as its Dean until 2010. His research has focused on health technology assessment (HTA) and he has published widely in that area, contributing to the development of methods of HTA. In addition, he has carried out research and conducted HTAs in many different therapeutic areas.

Ron was a founding member of the National Institute for Clinical Excellence (NICE) Appraisal Committee, serving on it for 7 years; served on the NICE Topic Selection Committee and the NICE Public Health Interventions Advisory Committee. He served for two years as a member of the Advisory Group on National Specialised Services (AGNSS), which advised the Secretary of State for Health on organization of services for people with very rare conditions. He is currently a member of the NICE Diagnostics Advisory Committee; the NICE Highly Specialised Technologies Evaluation Committee and NHS England's Rare Disease Advisory Group. Past activities included a two-year period as an Economic Advisor in the Department of Health; a 5-year period as economic advisor to The North Western Regional Health Authority, 7 years as founding director of the York Health Economics Consortium, and 3 years as a Specialist Advisor to the House of Commons Health Select Committee.

Professor Akehurst's academic interests include all aspects of health economics; application of microeconomic theory to problems of evaluation, production and behavior in a health context; using economic evaluative methodology to assist health care decision making; and getting more health output from the clinical research base.

Professor Akehurst is Strategic Director of BresMed Health Solutions, a healthcare consultancy specializing in Health Economics and Market Access for Drugs, Devices and Diagnostics.

Yann Le Cam

Chief Executive Officer, European Organisation for Rare Diseases – EURORDIS – Rare Diseases Europe

Yann Le Cam has dedicated 25 years of professional and personal commitment to health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, HIV/AIDS and rare diseases.

He was one of the founding members of EURORDIS in 1997, and was nominated Chief Executive Officer in 2001. He has participated to the revision and adoption of European regulations having an impact on rare disease patients' life, including the EU Regulation on Orphan Drugs, December 1999.

Yann was one of three patient representatives appointed to the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) for 3 mandates, and served as its elected Vice Chairman from 2000 to 2006.

He served on the Management Board and Executive Committee of the French HTA agency ANAES now called HAS for 5 years.

He was elected Vice-Chair of the EU Committee of Experts on Rare Diseases (EUCERD) for a three year mandate (2010-2013).

Yann holds an Executive MBA from the Hautes Etudes de Commerces – HEC – Jouy-en-Josas France (2000) and an MBA from the Institut Superieur de Gestion (1984), Paris, France.

Yann has three daughters, the eldest of whom has cystic fibrosis. He lives in France, Paris, and in Belgium, Brussels.

David Barnett

Emeritus Professor of Clinical Pharmacology University of Leicester

- Professor of Clinical Pharmacology University of Leicester
  (1984 -2009)
  Honorary Consultant Physician with a special interest in cardiovascular medicine at the University Hospitals of Leicester NHS Trust
  (1976 to 2009)
  Chair of the Specialist Advisory Committee for General Internal Medicine for the Royal College of Physicians
  (1996 to 2000)
- Chairman of the Appraisal Committee for the National Institute for Health and Clinical Excellence
  (1999 to 2009)
- Senior Mentor for NICE Fellows and Scholars programme
  (2010 to 2012)
- Independent consultant advisor to NICE Scientific Advice Programme

Flora Giorgio

Flora Giorgio is a pharmacist by training and works as policy officer at the European Commission in DG Health and Consumers (SANCO), Unit "eHealth and Health Technology Assessment". Within the Unit Flora works on the implementation of Article 15 on Health Technology Assessment of the Directive 2011/24/EU on "the application of patients' rights in cross-border healthcare".

Flora joined the European Commission in 2006 in DG Information Society and Media (Now DG CONNECT) and worked as policy and project officer in the ICT for Health Unit. Within the Unit she coordinated the policy activities, including relation with Member States representatives and stakeholders, the implementation of the Competitiveness and Innovation Programme and the European Innovation Partnership on Active and Healthy Ageing. She also managed several EU funded projects in the area of pharmaceuticals, patient safety and Electronic Health records.

Before joining the European Commission Flora, was for 5 years Secretary General of the PGEU, the European Association representing Community pharmacists. Flora also worked in a community pharmacy.

Richard Bergström

Director-General, EFPIA

Richard Bergström has been the Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA) since April 2011. Previously, he served for nine years as the Director-General of LIF, the Swedish Association of the Pharmaceutical Industry, following positions in Switzerland in regulatory affairs at the pharmaceutical companies Roche and Novartis.

Mr Bergström was also appointed by the Swedish Government to the Board of the Karolinska Institute.

He is a pharmacist by training, receiving his MScPharm degree from the University of Uppsala, Sweden in 1988.

Mel Walker

Vice President of Market Access Otsuka Pharmaceutical Europe

Dr Mel Walker BPharm MRPharmS PhD joined Otsuka's European executive team in 2012 with the task of building the market access function and Otsuka's organisational capability to meet the needs of healthcare systems in Europe. Mel is passionate about the role that a highly ethical and patient focussed pharmaceutical company can play in providing better healthcare for patients. He believes that value can be delivered not only by bringing medicines of real benefit but also by gaining a better understanding about how medicines should be used within healthcare systems. This knowledge can be used to optimise the value delivered to patients at both an individual and population level and position the industry as a trusted and valued partner in the delivery of healthcare.

Mel previously worked for GSK where he held a variety of senior roles including leading a team responsible for the delivery of health outcomes plans and reimbursement strategies for the oncology portfolio. He played a crucial role in driving engagement with international value experts involved in the appraisal, reimbursement and access for new medicines as part of the Access to Medicines Leadership, and helped to build broad access capability and drive customer centric approaches across the CE region as a member of the Executive Team.

Mel has co-authored over 30 research papers and abstracts, as well as 2 book chapters, and worked in several therapeutic areas including oncology, haematology, osteoporosis, rheumatoid arthritis, nephrology, transplantation, obesity, HIV and Alzheimer's disease. He regularly chairs and contributes to international conferences in the areas of market access, the HTA Regulatory interface, conditional reimbursement and customer centric approaches. He is affiliated to the Centre for Socioeconomic Research (University of Wales), sits on the Steering Committee for the Centre for Innovation in Regulatory Science, co-founded the HTAi ISG on HTA Regulatory Interactions and is a member of TOPRA's Advisory Council.

Niklas Hedberg

Niklas Hedberg is a pharmacist by training and is since 2009 Head of Department in the Department for Pharmaceutical Submissions at the governmental authority, the Dental and Pharmaceuticals Benefits Agency, in Sweden.

Niklas has been involved in the national decision making about price and reimbursement for pharmaceutical products since 2001. He has previously had positions as investigator, medical assessor, project leader and team leader.

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 11 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.

Leeza Osipenko

Senior Scientific Adviser, Scientific Advice Programme, NICE

Leeza manages a portfolio of fee-for-service scientific advice projects including parallel advice with regulatory agencies (EMA/MHRA) and leads on a number of strategic initiatives across the Institute and within the Scientific Advice Programme. She also holds an Honorary Fellow post at the University of Warwick Medical School. Leeza obtained a PhD in Systems Engineering from Stevens Institute of Technology (USA) in 2005 and joined the University of Warwick Medical School as Senior Research Fellow to conduct health economic evaluation of non-invasive prenatal diagnostic technologies. Prior to joining NICE, Leeza worked at a London-based public sector consultancy, Matrix Knowledge, as Principal Economist where she led on projects for the NICE Centre for Public Health Excellence and other public sector organisations. Leeza has a solid research and consulting background in health technology assessment and economic modelling.

Britta Paschen

Britta Paschen VP, Global Development & Medical / Head of Global Health Services Research, Merck Serono – Merck KGaA

Britta is Pharmacist by training (Johann Wolfgang von Goethe University, Frankfurt am Main, Germany) and accomplished post-graduate diploma and master studies in Business Administration, Economics & Financial Management (Technical University Mannheim), Health Economics (Stockholm School of Economics), Business Administration (London City School/Ashridge), and Health Outcomes Research (Harvard School of Public Health)

After joining Merck KGaA in 1987, she gained comprehensive professional experience in various international managerial and executive positions in the areas Production, Quality Assurance, Business Development, Strategic Marketing, Transfer Pricing, Health Economics, and Operational and Strategic Pricing. Britta was involved in Merck's acquisition of a generics business (Merck Generics), which was sold in 2007, the start up and roll out of Merck's Oncology Business and she has built up the company's organizational structures and capabilities in Pricing & Reimbursement, Health Economics, Health Outcomes Research and Market Access. Currently Britta Paschen is the Head of Global Health Services Research within Merck KGaA's Pharmaceutical Division (Merck Serono) and reports to the Global Head of R&D. Put in place in Q1 2012, Global Health Services Research is integral in driving value recognition for Merck Serono's portfolio assets and brands, to maximize access and reimbursement opportunities for the benefit of patients

Britta's main areas of professional interest comprise healthcare systems analysis, funding and organization of health services, operational and strategic value based pricing & reimbursement (P&R), health economics, market access, health outcomes research and health technology assessment (HTA) requirements and proceedings. Within Merck Serono, Britta does closely collaborate with all R&D platforms and Commercial Franchises. Currently her main focus is on Oncology and Neurodegenerative Diseases.

Paolo Daniele Siviero

Coordinator of the “Economic Strategy and Pharmaceutical Policy” area that comprehends the departments of:

1. Pharmaceutical Policy
2. Pricing and Reimbursement
3. Medicines Utilization and HTA
4. Consultative Bodies Secretariat

Italian Alternate Member of the European Medicines Agency (EMA) Management Board.

Vice-President of MEDEV group (2014 Incoming President).

Secretary of the Technical and Scientific Committee of the Italian Medicines Agency

Secretary of the Pricing and Reimbursement Committee of the Italian Medicines Agency

Mr. Siviero is also the Head of the Pharmaceutical Policy department of the Italian Medicines Agency (AIFA).

The main objective of the Pharmaceutical Policy department is to perform and evaluate studies and researches on the pharmaceutical sector. This task is accomplished through the coordination with other departments inside the Agency. The primary objective is to supervise the main activities of the Agency in the economic field and to define the pricing and reimbursement scheme for new pharmaceutical products, taking into account the analysis of other European agencies.

Furthermore, as coordinator of the “Economic Strategy and Pharmaceutical Policy” department, Mr. Siviero is responsible to anticipate and analyze critical aspects related to the sustainability of the National Health System concerning the pharmaceutical sector, both in the short run and in the long run. In order to achieve this purpose, it is fundamental to propose and implement specific strategies of intervention. In particular, those strategies are focused on defining models in order to:

1. encourage investments on R&D in the pharmaceutical sector in Italy;
2. promote regulations in favour of generic medicines;
3. forecast the effects of technological innovations, population trend variations and allocation of resources, both on health and on pharmaceutical expenditure;

4. propose a new pricing and reimbursement system.

During his career, Mr. Siviero has cooperated several years with the National Research Council, in particular with the research Institute of neurobiology and molecular medicine (INMM), regarding the development of issues such as the technological transfer, knowledge management and the economical valorization of results obtained through researches. He cooperated on the same topic with the Department of Experimental Medicine and Biochemical Sciences of the University “Tor Vergata” of Rome.

Furthermore, during his career Mr. Siviero has been CEO in companies dealing with communication and public relations in the health sector.

Judith Creba

Head EU Liaison & Policy, Regulatory Affairs, Novartis, Switzerland

Judith holds a PhD in Biochemistry from Birmingham University (UK) and worked for 5 years in Research in the Pharmaceutical Industry in the areas of Neuroscience, Cardiovascular and Metabolism before joining the Regulatory Affairs group at Novartis in Basel.

Judith has 20 years' experience in drug development, regulatory affairs and strategy. She has worked in a range of therapeutic areas, including Oncology, Infectious Diseases, Cardiovascular and Metabolism where she has been involved in the development and approval of a number of products, as well as post -marketing activities. Judith has been responsible for EU Regulatory Liaison and Policy since 2007 and represents Novartis on a number of EFPIA groups including Regulatory, Clinical trials and Paediatrics

Christine Mayer-Nicolai

Senior Director Global Regulatory & Scientific Policy, Merck Serono

Dr. Christine Mayer-Nicolai is heading Regulatory & Scientific Policy Europe within Merck Serono. Activities comprise leading the development of Merck Serono EU regulatory policy priorities and advocacy agenda, identifiying and responding to EU regulatory/legislative issues that impact research, development and lifecycle management and driving the Merck Serono advocacy agenda through participation on critical EU based committees and coalitions.

Christine joined Merck KGaA in July 2002 leading the group responsible for submissions in Germany and EU Coordination in coordinating processes between the global and local Regulatory Affairs departments for Merck KGaA and subsequently for Merck Serono. In 2004 Christine resumed responsibility for Global Regulatory Intelligence at Merck KGaA and expanded her role to cover policy in 2012.

After starting her career in Regulatory Affairs at Allergan, Christine headed the section Regulatory Affairs at the German Association of Pharmaceutical Industry (Bundesverband der Pharmazeutischen Industrie/BPI) 1995 until 2002, where she was in charge of developing industry position papers regarding new regulations for centralised, decentralised and national authorisations for the full range of different medicinal products.

Christine studied pharmacy at the Johann-Wolfgang-von-Goethe University in Frankfurt and holds a PhD from the Julius-Maximilians-*Universität* Würzburg.

Lectureship and membership in organizations:

- Lecturer at the Post Graduate Course “Master of Drug Regulatory Affairs” at the university of Bonn
- Vice Chair of DGRA (Deutsche Gesellschaft für Regulatory Affairs)
- Fellow and member of TOPRA (European RA professional organization)

Adrian Griffin

VP, HTA Policy, Johnson & Johnson

Adrian Griffin is Vice President, HTA & Market Access Policy at Johnson & Johnson. He has been involved in the fields of health economics, outcomes research, and reimbursement policy within the healthcare industry for 16 years, with experience across the pharmaceutical, medical device, and diagnostic sectors.

Adrian currently serves on one of the NICE Technology Appraisal Committee's, and is on the Board of Directors of ISPOR, (the International Society for Pharmacoeconomics and Outcomes Research).

Paolo Morgese

Director of European Research, Deerfield Institute

Paolo Morgese has been Director of European Research at the Deerfield Institute since August 2012 where he focuses on all the regulatory and market access activities in Europe and coordinates European research. In the previous 11 years, he had worked in HTA related roles at Merck Serono, Kyphon and Agenas.

Currently, Paolo is chair of the EuropaBio HTA Topic Group and member of the EUnetHTA Joint Action 2 Stakeholder Forum.

Paolo holds an MSc in Financial and Business Economics from the University of Essex, United Kingdom and a Laurea in Economics from the University of Siena, Italy.

Mira Pavlovic-Ganascia

Mira Pavlovic-Ganascia, MD practicing physician and Deputy Director for Health Technology Assessment at the Hauté Autorité de Santé (HAS), France, in charge of European activities related to health technology assessment (HTA), in particular those coordinated by the EUnetHTA. HAS is the EUnetHTA JA2WP7 lead partner for activities related to early dialogues with developers, disease-specific guidelines and methodology of assessment for reimbursement purposes. In this framework, Mira Pavlovic is coordinating the SEED (Shaping European Early Dialogues) project, financed by European Commission.

Previously involved in regulatory science for more than 10 years; Head of Scientific Advice Unit at the French Medicines Agency (AFSSAPS), Vice-Chair of Scientific Advice Working Party (SAWP), a member of Efficacy Working Party (EWP), and Biosimilar Medicinal Products Working Party (BMWP) at the EMA.

Jan Mueller-Berghaus

Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines, Langen, Germany

Professional CV:

Jan Mueller-Berghaus is member of the Scientific Advice Working Party (SAWP) since 2009 and in 2011 he was elected as co-opted member of the Committee for Medicinal Products for Human Use (CHMP). He is paediatrician by training and joined the Paul-Ehrlich-Institut (Germany) as clinical expert in 2005. The Paul-Ehrlich-Institut is the German Federal Agency for vaccines and biomedicines and is actively participating in all aspects of German and European marketing authorisation as well as clinical trial authorisation.

Prior experience includes basic research in immunology and translational research in the immunotherapy of cancer.

Seren Phillips

Associate Director

Seren Phillips joined NICE in January 2002 as Associate Director for the Technology Appraisals Programme where she was responsible for the delivery of a portfolio of Technology Appraisals. Prior to joining NICE, she worked for GlaxoSmithKline and she has extensive experience in the pharmaceutical industry in a variety of roles in research, clinical research and health outcomes in the UK, France and the US.

Finn Boerlum Kristensen

Head of Coordinating Secretariat of European Network for Health Technology Assessment, EUnetHTA (www.eunethta.eu), in Danish Health and Medicines Authority, Copenhagen, since 2006. Chairman of the EUnetHTA Executive Committee since 2010. Adjunct professor in health services research and health technology assessment at University of Southern Denmark since 1999.

Formerly Head of Danish Centre for Health Technology Assessment (DACEHTA), Danish Health and Medicines Authority, Copenhagen 1997-2009. University graduate in medicine. PhD in Epidemiology. Primary care physician and specialist in Public Health. Chairman International Network of Agencies for Health Technology Assessment (INAHTA) 2003-06. Board Director, International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2011-13. Chairman ISPOR HTA Council from 2013.

Editor of Health Technology Assessment Handbook (English, translated), 2007 and chief editor of three peer reviewed publication series from DACEHTA 1998-2009. Numerous scientific publications in HTA, Health Services Research, epidemiology and Policy Analysis.

James Anderson

External Partnerships Director,

Government affairs, public policy & patient advocacy (GAPPPA)

Glaxosmithkline

James improves the way GSK develops and commercialises its products by working in partnership with stakeholders. Working collaboratively, he addresses significant health policy issues, often conducting pilots with stakeholders. For example, James led GSK's engagement with EU payers, politicians and HTA agencies, under the European Healthcare Innovation Leadership "Tapestry" Network, which delivered the first multi-country parallel advice process. He is building on this success, working with other stakeholders including EMA and EUnetHTA. James works with GSK R&D teams to drive proactive external engagement with stakeholders and patients.

James leads GSK advocacy in the area of Antimicrobial Resistance and worked with the EU Commission and other partners to create and launch the ground-breaking €220m Innovative Medicines Initiative (IMI) AMR project. Working with the Massachusetts Institute of Technology ('NEWDIGS') on Medicines Adaptive Pathways to Patients (MAPPs, or adaptive licensing), James aims to develop more streamlined regulatory/access pathways based on iterative data generation and systems approaches, having already secured a GSK pilot asset within this programme.

Prior to this, James has held a number of Commercial roles at GSK and Shire Pharmaceuticals, including leading a global product launch in nephrology, re-designing the GSK sales model and driving the growth of the vaccines franchise.

James is Vice-Chair of the industry Healthcare Taskforce advising the OECD. He has a MBA from Harvard Business School and a Molecular Biology degree from Cambridge.

Karen Facey

Karen Facey is a Chartered Statistician, Honorary Member of the Faculty of Public Health, Fellow of the Royal Society of Medicine and an Honorary Senior Research Fellow in the Department of Health Economics and HTA at the University of Glasgow.

Following a career in the pharmaceutical industry and as a senior statistical assessor at the MHRA, Karen went to Scotland in 2000 to be founding Chief Executive of the first national HTA Agency in Scotland. She established processes for full HTA and helped setup the Scottish Medicines Consortium to undertake rapid appraisal of all new medicines. Karen now works internationally as a consultant to all stakeholders on matters relating to HTA.

Karen was on the board of a regional payer/provider of health care in Scotland for eight years and is now a member of the Scottish Health Technologies Group, which provides national appraisal advice on all non-medicine technologies. She is a member of the UK Committee for Safety of Devices. Karen is a strong supporter of Health Technology Assessment International (HTAi) and was Chair of the HTAi Policy Forum from 2007-2010 and the HTAi Interest Group on patient/citizen involvement from 2005-2012.

Angelika Joos

Executive Director, Global Regulatory Policy, Merck Sharp & Dohme (Europe) Inc.

Angelika Joos is a licensed pharmacist. Since 2001, she is responsible for Regulatory Policy issues at Merck Sharp & Dohme's Regulatory Affairs department in Brussels. Over the past 17 years, Angelika has gained strategic as well as operational experience with all regulatory procedures and various products in different therapeutic areas.

In her current position as Executive Director, Global Regulatory Policy she is responsible for monitoring and implementing Regulatory Policies & Procedures and advising the company on Regulatory strategies.

She has over 10 years' experience in working with various trade associations and professional organisations. Since 2012 she represents MSD in the EFPIA Scientific Regulatory and Manufacturing Policy Committee. In addition, she is actively involved in international policy activities as MSD delegate in the IFPMA Regulatory& Technical Policy Committee. Her main interests are related to HTA, Clinical Trials, Pharmacovigilance and Paediatrics.

Jane Moseley

Scientific Officer in the European Medicines Agency (EMA)

Scientific Advice Office , Product Development and Scientific Support Department

Human Medicines Research and Development Support Division

Part of Team responsible for administration of Scientific Advice procedures at the EMA since 2009 including procedures involving orphan medicines, small and medium enterprises, advanced therapies, paediatric scientific advice, and parallel advice involving HTAs.

Professional background in ophthalmology, epidemiology and pharmaceutical regulation:

Completed medical degree Trinity College, Dublin, Fellowship of the Royal college of Ophthalmologists (FRCOphth) and Fellowship of the Royal college of Surgeons Ireland in ophthalmology (FRCSI Ophth), and MSc in Epidemiology at the London School of Hygiene and Tropical Medicine (LSHTM).

Previously medical assessor at the Medicines and Healthcare products Regulatory Agency (MHRA) 1999-2009 working in pharmacovigilance, pharmacoepidemiology, clinical trials, and licensing procedures.

Member of the Faculty of Pharmaceutical Medicine UK, and the UK General Medical Council (GMC) registered Physician with a Licence to Practice.

Spiros Vamvakas

Education: Medical Doctor (University of Würzburg, Germany)
Board-certified specialist in Pharmacology and Toxicology (Bavarian Chamber of Physicians)
Associate Professor for Pharmacology and Toxicology (University of Würzburg, Germany)
Career to date:

Since 1984 Spiros Vamvakas held positions in the Department of Pharmacology and Toxicology in the University Clinic of Würzburg and in the Department of Pharmacology at the Medical Centre of the University, Rochester NY, USA. He joined the European Medicines Agency in May 1999 and his major activities at the Agency in recent years included the establishment of Orphan Drug Designation and Scientific Advice/Protocol Assistance, the Qualification of Novel Methodologies and the Parallel Scientific Advice between Regulators and Health Technology Assessment Bodies.

Antje Behring

Desk officer, Pharmaceuticals Department, GBA, Germany

Dr. Antje Behring graduated with a PharmD and PhD in pharmaceutical science from the University of Munich, Germany. After working as consulting pharmacist for a German health insurance company, she joined Germany's Federal Joint Committee (Gemeinsamer Bundesausschuss) Pharmaceuticals Department. Since then she has been involved in introduction of the procedure for additional benefit assessments for new pharmaceutical products and is responsible for handling incoming dossiers and requests for consultation meetings with pharmaceutical companies concerning the additional benefit assessment.

Bertil Jonsson

Vice Chair of SAWP

More than 10 years as SAWP member. Senior clinical assessor at the MPA, Sweden, specialising in oncology, haematology, and antivirals.

Recently has been involved in many EMA HTA parallel scientific advice procedures.

Broad clinical experience with a focus on haematology.

Thibaut du Fayet

Vice President, Alliance & Project Management, Marketing

Vice President, Project Management & Marketing

Thibaut du Fayet joined Transgene in 2008 and is in charge of project management, alliance management and marketing at Transgene. From 2006 to 2008, he was responsible for marketing at Stallergenes. Prior to that, he held various positions in corporate strategy and business development at bioMérieux (2003 -2007) and Rhone-Poulenc (1999-2003). Prior to his industry experience, he spent six years working as a Management Consultant at Bossard/Gemini Consulting.

François Meyer

Dr. François Meyer currently serves the French National Authority for Health (HAS, *Haute Autorité de Santé*) as Advisor to the President, with a particular focus on International Affairs. He joined the HAS in 2005 as the Director of the Health Technology Assessment (HTA) Division. In 2003 he was appointed Head of the Secretariat General of the French Drug Appraisal Committee (Transparency Committee) by the French Minister of Health. François Meyer previously served 6 years as Deputy Director of the Medicines and Biologics Evaluation Division at the French Medicines Agency (ANSM). From 1992 to 1997, he worked within the R&D department of an international pharmaceutical company. Dr François Meyer earned his MD degree from the University of Montpellier Medical School in France. He subsequently served the teaching hospitals of Montpellier as a practicing physician in endocrinology, metabolic disorders and internal medicine.