biosimilar medicines

a medicines for europe sector group

19th Biosimilar Medicines Conference

THE FUTURE IS BIOLOGIC: STRENGTHENING BIOSIMILAR POLICY FOR BETTER HEALTH IN EUROPE

LEONARDO ROYAL HOTEL AMSTERDAM, 25-26 MAY 2023

Speaker, Chair and Panellists Biographies

Adrian van den Hoven - Director General, Medicines for Europe

Adrian van den Hoven has been director general of Medicines for Europe since September 2013.
In his role he focuses on stimulating competition in off-patent medicine markets, fostering access to medicine, reducing medicine shortages and addressing major health crises, supporting policy measures for sustainable pricing, promoting efficient regulatory standards, and developing a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value-added medicines industries. He is also member, and former president, of the European Medicines Verification Organization (EMVO) board for the implementation of serialization against falsified medicines, the vice-chair of the International Generic and Biosimilar medicines Association (IGBA) and a member of the joint industry advisory council of the Health Emergency and Response Authority (HERA).

Harald Mische - Deputy Head of Unit DG Competition, European Commission

Harald Mische is the Deputy Head of Unit "Medical products: quality, safety and innovation" in the European Commission's Directorate-General for Health and Food Safety (DG SANTE). The unit is in charge of EU level policy developments on quality, availability and affordability of medicines and supervises important aspects of the implementation of EU legislation and of the Pharmaceutical Strategy for Europe. He joined DG SANTE in 2021, after serving for almost 20 years in the European Commission's Directorate-General for Competition (DG COMP) in various positions - more recently, in the Pharma Unit dealing with EU antitrust enforcement and policy in the area of pharmaceuticals and health. Being a fully qualified lawyer, prior to joining the European Commission in 2002, Harald practiced EU competition and regulatory law as part of an international law firm in Brussels. He is a regular speaker on EU pharmaceuticals antitrust and regulatory issues and has authored various publications on this topic. Harald obtained a Ph.D. in EU Merger Control Law from the Eberhard-Karls-University of Tübingen, Germany.

Christian Schneider - Head of Biopharma Excellence and Chief Medical Officer, Biopharma

Christian K Schneider, M.D., is Vice President/Head of Biopharma Excellence and Chief Medical Officer (Biopharma) at PharmaLex. Before joining Biopharma Excellence in September 2021, Christian was interim Chief Scientific Officer at the UK's medical products regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). Between 2016 and 2021 he was Director of the National Institute for Biological Standards and Control (NIBSC), a specialist center within MHRA. Prior to his time at MHRA, Christian was Medical Head of Division Medicines Licensing & Availability at the Danish Medicines Agency; and formerly Head of Division EU Cooperation/Microbiology at the Paul-Ehrlich-Institut, Germany's Federal Agency for Vaccines and Biomedicines. Christian has also held various senior roles at the European Medicines Agency (EMA) in a delegated capacity, including Chair of EMA's Committee for Advanced Therapies (CAT), and member of EMA's Committee for Medicinal Products for Human Use (CHMP). For nine years he was Chair of EMA's Biosimilar Medicinal Products Working Party (BMWP), and former Rapporteur for CHMP's Guideline on biosimilar monoclonal antibodies. As a regulatory scientist, Christian has published 50+ articles in international, peer-reviewed journals.

Martin Schiestl - Global Head Regulatory Affairs Policy, Sandoz

Martin Schiestl received his doctoral degree in chemistry with a specialization in bioanalysis from the University of Innsbruck in Austria in 1996. In the same year, he started his work on Biosimilar medicines at Sandoz where he built up the analytical and pharmaceutical development departments in charge of the biosimilar portfolio and other biological medicines of Sandoz. He moved into the regulatory and policy field in 2009, further fostering regulatory sciences for biosimilar medicines and supporting development and licensing of Sandoz' biosimilar portfolio. In his current role, he is responsible for the Global Regulatory Affairs Policy at Sandoz Biopharmaceuticals.

Peter Richardson - Senior Quality Specialist, EMA

Dr Richardson is a pharmacist, with a Ph.D. in pharmaceutics from The Queens University, Belfast. He worked for a number of years in the pharmaceutical industry (1991-1998) in the UK and Italy in the area of formulation research and development, with companies such as Bristol-Myers Squibb, SmithKline Beecham, Pfizer and Serono, concentrated mainly on drug delivery and controlled release systems for small and large molecules.

He has worked for the UK MHRA as a pharmaceutical assessor (1998-2004), with time assessing chemical and abridged applications and wide ranging experience of biotechnology / biological applications. He was UK delegate for the CHMP Biologics Working Party prior to joining the European Medicines Agency, where he had roles of scientific administrator (2004-2010) and Head of Biologicals Section (2010-2013).

He was Head of Quality Office (2013 - 2021), managing the oversight of the many aspects relating to quality of chemical and biological medicinal products. Since 2021 he has continued to support, as scientific secretary, the Biologics and Biosimilar Medicines Working Parties at the European Medicines Agency.

Niklas Ekman, PhD - Head of Biological Section, FIMEA and Vice-chair of the Biosimilar medicines Working Party

Dr Niklas Ekman has a background in molecular cell and cancer biology. After joining the Finnish Medicines Agency in late 2006, he worked the next 11 years as a quality assessor for biological medicinal products with focus on biosimilars. His main activities and responsibilities included assessments of European Medicines Agency (EMA) centralized marketing authorization applications, scientific advices, as well as national clinical trial applications. Currently, Dr Ekman is the head of the biological section at the Finnish Medicines Agency. At EMA, Dr Ekman is the vice-chair of the Biosimilar Medicinal Products Working Party (BMWP) and the Finnish member of the Biologics Working Party (BWP). He is also involved in the work of the recently established Heads of Medicines Agencies (HMA) Biosimilar Working Group (BSWG).

Julie Maréchal-Jamil - Director Biosimilars Policy & Science, Medicines for Europe

Since October 2015, Julie has become the coordinator of the Biosimilar Medicines Group, a sector group of Medicines for Europe. Before that, Julie was part of Medicines for Europe's regulatory and scientific affairs team for 8 years, with responsibilities in the areas of Quality, Compliance, Environment, Health & Safety as well as Bioequivalence. MSc in Pharmacology by background, she previously worked for the pharmaceutical industry. Her work consists in the coordination of Biosimilar policy related activities and external liaison with policy makers, EU institutions, Medicines Agencies, International organisations, industry and professional associations as well as a broad range of stakeholders. Julie has gained experience in technical areas such as pharmaceutical development, project management, EU regulatory affairs as well as on EU pharmaceutical and health policies.

Lissy de Ridder - Paediatric gastroenterologist, Sophia Children Hospital, Erasmus University medical center

Dr Lissy de Ridder is Associate Professor in Pediatric Gastroenterology at Erasmus MC-Sophia Children's Hospital, Rotterdam. Her current research concerns pediatric inflammatory bowel disease (IBD) with a main focus on clinical and translational studies. She is particularly interested in the safety and efficacy of medical treatment of IBD. She is principal investigator and workpackage leader in Horizon 2020 application PIBD-SETQuality. This project concerns the generation of a high-powered and secured data base to collect and analysis of long-term real world data of children with IBD (inception cohort) in a prospective registry designed to analyze effectiveness and safety signals and correlate them to individual risk factors. Also, she is principal investigator of the pan-European safety registry, collecting rare and severe safety signals within pediatric IBD via a monthly E-card. Moreover, she is principal investigator and project leader of TISKids, a randomised controlled trial on top-down versus step-up treatment in newly diagnosed pediatric Crohn's disease. The TISKids study was the first pediatric study making use of an infliximab biosimilar. Also, she was in the lead of the first and the revised ESPGHAN position papers on the use of biosimilars in pediatric IBD. She is Vice Chair of the Dutch Paediatric Association, Scientific Secretary of ESPGHAN (European Society of Pediatric Gastroenterology, Hepatology and Nutrition), treasurer of PIBDnet, associate editor of JPGN (Journal of Pediatric Gastroenterology and Nutrition), former Chair of P-ECCO (Pediatric committee of European Crohn and Colitis Organization), and former secretary/current member of the ESPGHAN pediatric IBD Porto working group.

Aurelio Arias - Director, EMEA Thought Leadership, IQVIA

Aurelio creates topical and forward-looking strategic content relevant to pharma executives worldwide and publishes articles, blogs, and white papers on a regular basis. Aurelio's predominant focus is on off-patent markets where he generates evidence-led insights with a view to spark high-level discourse on biosimilars, generics and value added medicines.

Kate O'Regan - Communications & Stakeholder Relations Senior Manager, Medicines for Europe

Kate is the Head of Communications and Stakeholder Relations at Medicines for Europe, the trade association representing the generic, biosimilar and value-added medicines industry. Kate joined Medicines for Europe in 2017 after a number of years at the Association of European Cancer Leagues. Having worked more than ten years in the healthcare sector from within the European Parliament, industry, civil society NGO and trade association, Kate is a firm believer in the importance of European policy in boosting access to medicines.

Tanya Collin-Histed - International Gaucher Alliance

Tanya Collin-Histed became involved in the Gaucher world in 1996 when her daughter Maddie was diagnosed with Type 3 Gaucher disease. A year later she became a Trustee for the UK Gauchers Association and started to support patients and their families with Type II and III Gaucher Disease through family conferences, information booklets and proving friendship and emotional support. In 2001 Tanya received the Alan Gordon Memorial Award in recognition for her work with Neuronopathic Gaucher disease and her support to families. In 2003 Tanya became the national development manager for the UK Niemann-Pick Disease Group, the charities first ever employee. However, in 2005 she took up the post of Executive Director of the Gauchers Association UK and was in this post, as Chief Executive until July 2018 when she resigned to take on the role of Chief Executive Officer for the International Gaucher Alliance (IGA) on a full-time basis. Tanya took up the position as a Trustee of the UK Gauchers Association in October 2018.
Tanya has been the CEO of the IGA since 2008 and underpins all the activities of the IGA from the UK. In December 2017 Tanya became a Trustee of Medics4RareDiseases. Tanya resigned from M4RD in 2020 to be able to focus more on her work as a Trustee for the UK Gauchers Association. In June 2020, Tanya became the CEO of International GARDIAN Ltd (IGL). The IGL is a company wholly owned by the IGA that will own and govern the new Global patient nGD registry. The Gaucher Registry for Development, Innovation, and Analysis of Neuronopathic disease (GARDIAN) will study patients with GD2 and GD3 worldwide by collecting longitudinal data on self-reported symptom burden, functional status, and health-related quality of life (HRQOL) and well-being in a systematic and standardized manner.
In October 2022, Tanya resigned as a Trustee for the UK Gauchers Association to focus on her international work.
Outside of work Tanya's time is spent swimming , with friends and family or a good book.

Marta Wosinska - The Brookings Institution, USA

Marta E. Wosińska, Ph.D., is a visiting fellow at the USC-Brookings Schaeffer Initiative on Health Policy. She is a healthcare economist with a particular expertise in prescription drugs and experience spanning academia and federal government. Dr. Wosińska's government experience includes serving as director of the Bureau of Economics at the Federal Trade Commission, chief healthcare economist in the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services, and director of economics staff at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation & Research. Dr. Wosińska also served as economic advisor to the U.S. Senate Finance Committee, providing drug market analysis and expert guidance for the Committee's bipartisan investigative and legislative work on drug pricing. Among academic institutions, she was consulting professor and deputy director for policy at the Duke-Margolis Center for Health Policy at Duke University and an assistant professor of marketing at the Harvard Business School.

Fabrice Romanet - Vice Chair of the Biosimilar Medicines Sector Group, Medicines for Europe and SVP, Head of Program Leadership, Regulatory and Governmental Affairs - Biosimilars, Fresenius Kabi SwissBioSim GmbH

Fabrice Romanet is biologist by training and has worked in R&D within the pharmaceutical industry for over 17 years. Fabrice is now Senior Vice President responsible for heading up the global departments of Program Leadership, Regulatory Affairs and Healthcare Policy at Fresenius Kabi Biopharmaceuticals Business Unit with it's global HQ based in Eysin, Switzerland. Fresenius Kabi is a division of Fresenius SE which is a large, 100 year old, global healthcare company with over 310,000 employees and over 65 production facilities worldwide. Fresenius Kabi now have biosimilars approved in both the autoimmune and oncology domain and have a broad and exciting pipeline of future biosimilars. As an end-to-end developer, Fabrice is especially interested in delivering high quality, affordable biologics to healthcare systems around the world and has extensive experience in liaising with leading health agencies such as EMA, FDA, Health Canada, TGA and MHRA. As vice chair of the Biosimilars Medicine Group of Medicines for Europe and active member of the US associations AAM and Biosimilar Forum, Fabrice has a keen interest in pursuing science-led evolution of regulatory development biosimilar guidelines. Fabrice believes that streamlining the root to approval for biosimilars is of paramount importance to futureproof biosimilars.

Michael Rosu-Myles – Adjunct Professor, Health Canada

Dr. Rosu-Myles is the Director for the Centre for Biologics Evaluation and the lead for the Health Canada lead for the World Health Organization Collaborating Centre for the Standardization and Evaluation of Biologicals. He manages a team who engage in cutting edge research and product evaluation and testing to support regulatory decisions on the authorization of clinical trials and market access for biologics and biosimilars in the oncology space as well as cell and gene therapies and radiopharmaceuticals. Dr. Rosu-Myles received his Ph.D. in Immunology and Microbiology from the University of Western Ontario and was trained as a post-doctoral fellow at the National Cancer Institute in the US National Institutes of Health prior to being recruited to Health Canada to establish a stem cell research program in 2008. Since starting as Director in 2018 Dr. Rosu-Myles has played a leadership role in the implementation of Health Canada's Advanced Therapy Regulations and their response to the COVID-19 pandemic.

Stacey Ricci - Director of the Scientific Review Staff, Office of Therapeutic Biologics and Biosimilars, FDA's Center for Drug Evaluation and Research

For over 17 years, Dr. Ricci's work at U.S. FDA has focused on the scientific and regulatory review of biotechnology-derived therapeutic proteins. She has made major contributions to FDA guidance and standards development for biosimilars and other protein therapeutics. As Director of the Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars, Dr. Ricci leads a multidisciplinary team of scientists, clinicians, pharmacists, and project managers who oversee the review of biosimilar and interchangeable products at all stages of development and who advance biosimilar policy and scientific standards development through regulatory scientific research activities, facilitating scientific dialogue and stakeholder engagement, and providing educational and training opportunities.

Yasuhiro Kishioka - Review Director, Office of Cellular and Tissue-based Products Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Kishioka is currently Review Director of the Office of Cellular and Tissue-based Products, PMDA. Since joining PMDA in 2008, Dr. Kishioka has worked in the Office of Cellular and Tissue-based Products where his responsibilities were the quality review of biotechnological/biological products and the review of biosimilars. He has been actively engaged in various international activities on these areas such as WHO, APEC, ICH and IPRP. From April 2019 to March 2022 he also worked in Office of International Programs and served as ICH Technical Coordinator and MHLW/PMDA international liaison official. He obtained a Ph.D. from Hokkaido University in Meat Science with emphasis in Molecular Biology.

Steffen Thirstrup – Chief Medical Officer, EMA

Steffen Thirstrup is a medical doctor and board-certified specialist in clinical pharmacology and therapeutics. He holds a PhD in pharmacology and has a long background in clinical internal medicine with special emphasis on adult respiratory medicine. Additionally, Dr. Thirstrup was appointed adjunct professor in pharmacotherapy at the Faculty of Health Sciences, University of Copenhagen, in 2012. From 2004-09 Steffen Thirstrup worked at Danish Medicines Agency first as the Danish member of CHMP at the European Medicines Agency (EMA) for five years including 10 months as joint CHMP- and CAT-member, followed by a short period as head of Danish Institute for Rational Pharmacotherapy dealing with HTA and best practice guidelines for primary care. In 2011 Prof. Thirstrup rejoined the licensing division at the Danish Medicines Agency acting as Head of Division for Medicines Assessment and Clinical

Trials. During this period Prof Thirstrup co-chaired the European Commission's working group on market access for biosimilars medicinal products and acted as key scientific contact for the managing entity of the IMI beneficiaries for the PROTECT collaboration (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium). In March 2013, Prof Thirstrup joined the pharmaceutical consultancy company NDA Group AB as a full-time medical advisor on NDA's regulatory advisory board. In April 2014 Prof Thirstrup was appointed as director for the Regulatory Advisory Board at NDA Regulatory Services Ltd. Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands. Prof Thirstrup is author of more than 30 scientific papers, guidelines and text-book chapters as well as co-editor of 5th edition of Basal og Klinisk Farmakologi (Medical school pharmacology textbook in Danish). Prof Thirstrup shares his life between Amsterdam and with his family in a small community (Værløse) just outside Copenhagen, Denmark.

Magnus Bodin - BMAC Vice chair and Head of Biosimilar Market Access, Biogen

Mr. Bodin is currently Senior Director and Head of Biosimilars Market Access for the ECP (Europe, Canada and Partner Markets) and Intercontinental Regions at Biogen. In his role, he leads the work on Pricing, Tenders & Contracts, Sustainability and Policy for the Biosimilar Business Unit. Mr. Bodin has more than 15 years of experience from the life sciences industry, across several therapeutic areas and geographies. He started his career in Strategy Consulting, advising both Governments and large corporation, and later held various commercial roles in the biotech and pharmaceutical industry before joining Biogen in 2017. Mr. Bodin is a Swedish and Swiss dual citizen and holds a Master's Degree in Physics from Chalmers University of Technology in Gothenburg, Sweden.

Laure Geslin - DG Sante, European Commission

Laure Geslin is Policy Officer at the European Commission's Directorate-General for Health and Food Safety (DG SANTE). She is leading a team focused on EU level policy developments related to the accessibility, affordability, and availability of medicines, and is responsible for steering EU-wide cooperation in relation to pricing and reimbursement of medicines. Prior to this role, Laure served as Head of Division for Proper Use at the Belgian Federal Agency for Medicines and Health Products (FAMHP), where she chaired the Belgian Task Force for Medicines Shortages and represented the agency in the EMA/HMA Task Force on Availability of Authorised Medicines and the Belgian Pricing Committee for Pharmaceutical Products. She previously worked as Director of Tarification Services and Professional Development and Defence at Pharmacy. Brussels, and advocated for community pharmacists in Brussels. Laure started her career as community pharmacist and holds a Master's degree in Pharmaceutical Science from the University of Ghent, Belgium.

Neil Grubert - Independent Global Market Access Consultant, UK

Neil Grubert is an independent market access consultant and author with 30 years of experience tracking global drug markets. Prior to his current role, he spearheaded the Decision Resources' internal market access business, most recently as Vice President, Global Market Access Insights. He formed the Future of Pharmaceutical Market Access forum and posts on topical market access issues on LinkedIn on a daily basis.

Despoina Makridaki - President of Panhellenic Association of Hospital Pharmacists (PEFNI)

Despoina Makridaki holds a degree in Pharmacy and an MSc in Clinical Pharmacy from the School of Pharmacy, National and Kapodistrian University of Athens and is completing an MBA in Management of Healthcare units, from the National School of Public Health in Athens. She is Director of Pharmacy Services at the "Sismanoglio - Amalia Fleming" General Hospital of Atttica (Greece), Director of Professional Development at the European Association of Hospital Pharmacists (EAHP) since June 2017 and Member of E.A.H.P's Scientific Committee since December 2014.
She was appointed as 1st Vice President of National Organization for Medicines (E.O.F) in the period April 2015-June 2018. President of Panhellenic Association of Hospital Pharmacists (PEFNI) since May 2013 and Member of the Advisory Board of Pharmacy School of University of Athens, regarding undergraduate and postgraduate studies, from 2019 onwards. Member of the National Committee for the Surveillance of Pharmaceutical Expenditure and Therapeutic protocols since May 2015. Member of the Central Health Council in Greece since 2022, and member of the Working Group for the advancement of Clinical Studies and Biomedical Research – organized by the Greek Ministry of Health in 2022. She is Chairman of the Pharmacy and Therapeutics Committee and Pharmacovigilance Committee and coordinator of the COVID-19 Vaccination Centres in the Hospital Complex "Sismanoglio-Amalia Fleming"General Hospital of Attica, coordinator of management of oral antiviral and monoclonal antibodies' therapies against Covid-19 in Attica region. EAHP Board Lead for countries Greece, Latvia, Lithuania and Estonia. She is EAHP's representative at the EMA's Healthcare Professionals' Working Party, at EU-HERA as member of Civil Society Forum and at EU SANTE-HTA-Stakeholder Network. Her EAHP portfolio (as leader or co-leader) includes Access to medicine, Pricing and Health Technology Assessment, Biologics, Common Training Framework Working Groups, Recruitment and Mobilization of members, Clinical Trials, Compounding/ready to use preparations/hazardous drugs, Advanced Therapy Medicinal Products and Orphan drugs and Procurement.

Ainhoa Aranguren – Madrid Regional Department of Pharmacy and Medical Devices, Madrid Health Service SERMAS, Spain

Ainhoa is currently the Chief of the Pharmaceutical Planning, Projects and Purchasing Area within the Madrid Regional Pharmacy Department (SERMAS, Servicio Madrileño de Salud), Madrid Health Service Organization. She became a Hospital Pharmacist in 2000 and worked as such until 2013 in different hospitals in the Madrid Community. During this period, she was involved in different subjects such as drug compounding area, pre-graduate and post-graduate training, drug purchase and consumption management areas among others. In her hospital pharmacist position, she also was a member of several Antimicrobial Policy Committees and the Biological Therapies Unit in La Princesa University Hospital. In her current job, she has been in charge of different matters related to Pharmaceutical Planning and Projects in Public Hospital and Primary Care settings. She also coordinates centralised purchase procedures such as Framework Agreements related to medicines and medical devices to be used in Hospitals or Primary Care, including biological and biosimilar drugs. She is involved in coordinating a Pharmaceutical Care Program in public Nursing Homes and Disability Centres. She is also the Secretary of the Madrid Assessment Committee for Growth Hormone and Related Substances. Biosimilar Drugs use support in Madrid Health System is one of the key strategies of the Madrid Regional Pharmacy Department in which she is directly involved. A multidisciplinary approach that considers centralized purchasing, communication to healthcare professionals, biosimilar medicines use monitoring and promotion, incentives for health care professionals, or information addressed to patients and citizens is being carried out. Overall, all the above-mentioned initiatives aim to implement a rational and increasing use of biosimilar drugs in the Madrid's health care system.

Fernando de Mora - Professor of Pharmacology/Consultant on Biosimilars, UAB-Universitat Autònoma de Barcelona - Spain

Fernando Fernando de Mora, PhD, MBA, is Full Professor of Pharmacology at the Universidad Autónoma de Barcelona (UAB) in Spain, where he lectures undergraduate and postgraduate students in pharmacology and biotechnology and conducts research in immunopharmacology (asthma and allergy), with a number of international publications. Between 1988 and 1998, Dr. de Mora retained various Biomedical Research Positions in Spain, the Netherlands (University of Utrecht), the UK (University of Southampton) and USA. During this time, he completed his PhD in Immunopharmacology (1993, UAB, Spain), a Postdoc at Harvard Medical School, USA (1994-1997), and his Master of Business Administration (MBA) from the University of Chicago, USA (1999). Between 2005 and 2011 he was the Chairman of the Pharmacology Dept. at the UAB's Medical School. Since 2008, he has worked as an International Academic Speaker and Consultant in biosimilars science regulation and market. He was invited by the United Nations as an international expert and also as a speaker and chairman in major biosimilar conferences globally. Dr. de Mora has collaborated worldwide with Ministries of Health, and has acted as a consultant for numerous pharma companies, in many cases as a member of their Scientific Advisory Board. Between 2009 and 2012 he was Managing Director of Salupharma Biosimilars SA, a university spin-off aimed at early stage biosimilar development.

Prof. Milan Lukáš - IBD Clinical and Research Centre ISCARE and 1st Medical Faculty, Charles University, Czech Republic

Prof. Milan Lukáš, MD, CSc., AGAF was born in 1959 in Tábor. He graduated from the 1st Faculty of Medicine, Charles University Prague in 1984. He passed his board examination in gastroenterology in 1993. From 1993, he worked at the General Teaching Hospital in Prague, at the Clinic of Internal Medicine, specialising in inflammatory bowel disease. He has been the head of the ISCARE clinic since 2007 and he is also the Sr. Consultant of the ISACRE Clinical and Research Centre for Inflammatory Bowel Disease. Prof. Lukáš is the author of more than 250 publications in both Czech and foreign medical journals. He is the past president of the Czech Gastroenterological Society and editor-in-chief of the journal "Gastroenterologie a hepatologie." He is a member of several international organisations, including the American Gastroenterological Association, the European Crohn's and Colitis Association and the International Organization for the Study of Inflammatory Bowel Disease.

Peter Taylor - Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK

Peter C. Taylor holds the Norman Collisson chair of musculoskeletal sciences at the University of Oxford. He studied pre-clinical medical sciences at Gonville and Caius College at the University of Cambridge and his first degree was a BA(Cantab) Physiology in 1982. He subsequently studied clinical medicine at the University of Oxford and graduated in 1985 with BM and BCh degrees. He was awarded a PhD degree in 1996 from the University of London for research on pathogenesis of arthritis and was elected a Fellow of the Royal College of Physicians in 2000 and a distinguished member of the British Society for Rheumatology in 2016 and delivered the Heberden Round that year. Professor Taylor was a founder member and chaired the UK government and NIHR Translational Research Partnership in rheumatology from 2015-18, bringing together the UK's leading academic and clinical centres for experimental medicine and translational research into a ready-formed partnership of Universities and NHS hospitals. Professor Taylor has specialist clinical interests in inflammatory arthritis. He has over thirty years' experience in clinical trial design and international leadership in studies of biologic and small molecular therapies in rheumatoid arthritis and ankylosing spondylitis including the earliest seminal trials of anti-TNF and anti-IL-6 receptor therapy. In experimental medicine studies, Professor Taylor employs targeted therapies as probes of pathogenesis to investigate the in vivo biology of the target in the pathobiology of the disease phenotype under in vestigation. His related research expertise includes investigation of mechanisms sustaining inflammation and development of novel outcome measurements for application in assessment of response to therapy, including ultrasonographic, PET and high-field magnetic resonance imaging technology. His interest in novel outcome measures also includes new tools for the personalised assessment of well-being which can be used adjunctively to clinical outcome measures in informing management decisions.

Mourad Farouk Rezk - Vice president- Global head of medical affairs and development, Biogen Biosimilars

Dr Mourad Rezk joined Biogen in January 2015. He is a medical doctor who trained as a diabetologist. He brings more than 20 years of experience in the pharmaceutical industry, holding a number of leadership roles in medical affairs, R&D and marketing. Before joining Biogen, Dr Rezk was with Amgen for nearly eight years as an international medical lead for nephrology innovator biologics and the company's EU biosimilars taskforce. While there, he established an internal biosimilars medical platform and led the development and execution of a significant number of multinational studies, key publications and poster presentations. He has also spoken at a number of key international biosimilars congresses. Prior to that, Dr Rezk spent four years in Athens with Novo Nordisk Africa & Gulf as the region's medical affairs director, establishing diabetes and hematology clinical and medical educational infrastructures that supported the launch of the company's second-generation insulin analogues and hemophilia treatments. He also previously spent nearly 11 years with J&J Middle East where he was marketing & sales lead for the biotech business unit, after which he moved to head the medical affairs team.

Liese Barbier - Postdoctoral Researcher Pharmaceutical Sciences, KU Leuven, Belgium

Liese Barbier, PharmD, PhD, is a postdoctoral researcher at the Clinical Pharmacology and Pharmacotherapy research Unit at the KU Leuven (Leuven, Belgium). She holds a Master degree in Pharmaceutical Sciences and obtained her PhD in Pharmaceutical Sciences. She is part of the KU Leuven-Erasmus MC founded MABEL Research Fund. The MABEL Fund is an academic research group focussing on investigating market dynamics of off-patent biologicals and biosimilars. In 2021, Liese obtained her PhD on the topic ''Sustainable biosimilar competition: clinical, regulatory and policy insights'', investigating biosimilar evaluation and market entry in Europe from a regulatory, clinical and policy lens through mixed-methods research involving document analysis, literature review and quantitative as well as quantitative techniques such as stakeholder interviews, focus group discussions and consensus methods. Her research interests currently focus on optimizing clinical, regulatory and policy frameworks, especially in the context of biosimilar medicines, and by investigating ways on how decision-making along the drug life cycle can be more unmet need driven and patient informed. She teaches at the KU Leuven on regulatory evaluation and processes, and regulatory and clinical implementation aspects of biosimilar medicines. Furthermore, she (co-)supervises several PhD and Master students in the area of biosimilars, patient preferences and unmet need driven policy making. In 2019, Liese was seconded to the European Medicines Agency (London the UK & Amsterdam, the Netherlands), where she was part of the Oncology, Haematology and Diagnostics Office of the Human Medicines Division. Here she was involved in initial marketing authorization applications of monoclonal antibody biosimilars in oncology as product lead, and provided scientific support to biosimilar initiatives across the agency, working with the Biosimilar Matrix, the Biosimilar Medicinal Products Working Party as EMA liaison and the broader international cluster. End of 2022, Liese joined the METRICs research group at Stanford University (California, the US) as visiting researcher for a three-month stay to expand on methodological (meta-research) techniques applicable to the regulatory science research field.

Dan Cohen - Vice President & Head of Biosimilars, Europe and Canada, Biogen

Dan is Vice President and Head of Biosimilars ECP (Europe, Canada and partner markets) at Biogen. Dan has more than 20 years experience in the pharmaceutical industry including 17 years at Eli Lilly and 5 years at Biogen, across multiple therapeutic areas including Immunology, Ophthalmology, Mental Health, Diabetes and Alzheimer's. Dan has worked extensively with in-market and pre-commercial assets, and through his career has led country, European and Global teams. For the last 5 years working with biosimilars, continuing a deep passion for increasing patient access, delivering value and enabling healthcare systems across Europe and Canada. Dan has a BA (Hons) in Commerce from Napier University, Edinburgh, is a qualified CIPD practitioner, and a certified Black Belt in Lean Six Sigma.

Xavier Mesrobian - Senior Vice President Commercial EMENA, Accord Healthcare, Biosimilar medicines Market Access Committee, Biosimilar medicines group & Vice President Public Affairs Europe, Middle East and North Africa

Xavier has over 20 years' experience in the pharmaceutical industry. After graduating with a PharmD Degree and a Master of Science in applied Pharmacoeconomics, Xavier conducted numerous research projects in Patient Reported Outcomes and Health Economics with Mapi Values, a Boston, Massachusetts based consulting company. Xavier's pharmaceutical experience started at Sanofi, where he first led the Pharmacoeconomics team in the "rest of the world" region. After completing an Executive MBA, Xavier was appointed as Head of Global Marketing for Zentiva – a Sanofi company. He then became Head of Generics and Classic Business in the Africa region. Xavier joined Accord Healthcare in 2015, initially as Cluster Director for Accord France and BENELUX, where he designed and implemented leading pivotal projects within the geography including launching Accord first ever Value-Added Medicine in the Netherlands and its first biosimilar in France. In 2022, Xavier was appointed Senior Vice President Commercial in Europe, Middle-East and North Africa.

Harshika Sarbajna – VP and Head Commercial, Global, Alvotech

Harshika is a seasoned leader with 20 years of experience in various leadership roles overseeing Marketing & Sales, Market Access, P&L Management and Strategy - have deep understanding of the end-to-end business operations in Biosimilars and Generics across US, Europe, and Asia. In her current role at Alvotech, Harshika is responsible for the overall business P&L, launches and strategic partner development globally. She is also spearheading all commercial efforts including Market access, customer and partner engagements with strategic partners. In her last role at Sandoz, Harshika had full P&L responsibility of multiple biosimilars and specialty generics brands in US, including launches between 2023-2025. Before that, she has held positions within Sandoz as the Global Marketing & Sales Head for Anti-

infectives & Specialty business, and Global Head of Strategy and Operations for Biosimilars business, working closely with key markets & cross-functional leadership teams to achieve ambitious topline & bottom-line targets. Previously, she has held multiple leadership roles across various pharma organizations and consulting firms in different geographies.

Kyung-Ah Kim - Executive Vice President, Development Division Leader, Samsung Bioepis

Kyung-Ah Kim is Executive Vice President and Leader of Development Division at Samsung Bioepis. Kyung-Ah, a veteran scientist with more than 20 years of experience in biologic development, is responsible for overseeing all of Samsung Bioepis' product development across various therapeutic areas. Prior to joining Samsung Bioepis, Kyung-Ah worked as Principal Scientist and later as Vice President at Samsung Advanced Institute of Technology (SAIT) leading Biotherapeutics Group focusing on development of antibody therapeutics targeting oncology. Before joining SAIT, she worked as a scientist/head of cell biology at multiple biopharmaceutical companies, leading various projects on development of therapeutic agents, including genetic sequencing and profiling, development of drug screening assays, pre-clinical assessment, pharmacological assessment, and functional assessment of antibodies. Kyung-Ah holds Ph.D, in neurotoxicology from The Johns Hopkins University where she established signal transduction pathway, specifically in the learning impairment caused by genetic perturbation in lead poisoning.'

Darius Panaligan - Fresenius Kabi Biosim

Darius currently serves as Senior Vice President and Head of Commercial for Fresenius Kabi Biopharma in EU and ROW. Darius oversees the growth and development of the Biosimilar business across markets and has led the launch of the franchise since joining Fresenius Kabi in 2017. Darius also leads the Global Strategic Marketing and Communications function for the Business Unit and in this capacity supports all New Product Development and Launches including the US market. Darius brings more than 20 years of experience in the pharmaceutical industry from Novartis, Sandoz and Merck KgaA in Global, Regional and Local capacities. Darius completed Molecular Biology at the University of British Columbia where he worked in research and post-graduate education. He also obtained an MBA from Simon Fraser University Canada and Manchester Business School in the UK.

Peter Stenico - Global Head Biosimilars, Sandoz

Peter Stenico was appointed Global Head Biosimilars at Sandoz in January 2023 and since then has led the global biosimilar strategy and activities for the company. Previously, he held the position of Country Head and General Manager for Sandoz in Germany and is also the former President of the German Generics Association (Pro Generika). Peter joined Sandoz in 2002 and, over the past two decades, has gained broad GX and Biosimilar industry experience through various roles covering Strategy, M&A, Commercial on Global, Regional (Europe) and Local (Austria, Italy, Germany) level. He has a strong passion to foster broader access for patients and supports the development of the long-term viability of the biosimilar and generic industry. Peter studied Economics at the University of Innsbruck (AT) and Leuven (BE) and obtained an MBA at SDA Bocconi Milan (IT). He is married and father of 2 sons.

Pekka Kurki - Adjunct Professor, University of Helsinki

Dr. Pekka Kurki, M.D, Ph.D, acted as a research professor at the Finnish Medicines Agency (Fimea) until retirement in June 2016. He has a teaching affiliation to the University of Helsinki (adjunct professor of clinical immunology). His scientific interest also includes cell biology, rheumatology and regulatory science, including biosimilars. 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 has also acted as an expert of the CHMP/BMWP and the WHO in drafting biosimilar guidelines.