Isabell Remus - Chair of the European Biosimilar Medicines Group

Isabell Remus currently serves as Head Biosimilars & Specialty Business for Sandoz in Europe. Under her leadership, Sandoz region Europe launched several biosimilars including adalimumab, etanercept and rituximab; making Sandoz the number one with eight market biosimilars. She is a member of the Biopharma Executive Committee as well as the Region Europe Leadership Team. Isabell is also the Chair of the Biosimilar Medicines sector group at Medicines for Europe. Since joining Novartis in 2005, Isabell has taken on roles of increasing responsibility across both Novartis and Sandoz, most recently serving as Head, Biopharmaceuticals Western Europe; Head, Global Product Strategy and Commercialization Biosimilars and Oncology Injectables and Chief Executive Officer Specialty of Hexal AG and Managing Director of Sandoz Pharmaceuticals GmbH. She has a breadth of proven leadership experience across global brand management, market access, commercial excellence, new products and portfolio over a variety of therapeutic areas including immunology, oncology, nephrology, gastroenterology and more. Prior to joining Novartis / Sandoz, Isabell Remus worked for Procter & Gamble in Athens, Geneva and Frankfurt. She studied European Business Administration in London and Reutlingen.

Michael Soldan – Senior Adviser

Experienced CEO and Board Member with a demonstrated history of working in the pharmaceuticals industry. Skilled in General Management, Clinical Research, Protein Chemistry, Life Sciences, Vaccines, and Oncology. Strong professional graduated from PhD.

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).

Ferenc Marofka, Policy Officer, Health Industrial Ecosystem, DG GROW, European Commission

Ferenc Marofka serves as a Policy Officer in the Directorate-General for Internal Market, Industry, Entrepreneurship, and SMEs (DG GROW) at the European Commission. In the Health Industrial Ecosystem team, he is tasked with integrating the competitiveness of the industry and the EU's strategic autonomy for critical health products into all relevant policies. From 2020 to 2023, Ferenc held a position in the Directorate-General for Health and Food Safety (DG SANTE), where he conducted economic analyses supporting the reform of the EU's pharmaceutical legislation. During this period, he also assisted the Commission's special task force on Covid-19 vaccines. Prior to his tenure at DG SANTE, he spent over eight years in the Directorate-General for Research & Innovation (DG RTD), focusing on health innovation policy. Before his engagement at the Commission, he worked for the pharmaceutical and medical devices industries.

Saskia van der Erf, Partner, Strategies in Regulated Markets (SiRM), The Netherlands

Saskia is a managing partner at boutique consultancy SiRM and a highly experienced healthcare project manager (~20 years). She is originally trained as a civil engineer. She worked in Singapore and in Paris, and before moving abroad at Dutch management consulting firm Andersson Elffers Felix. In Singapore, Saskia worked at Singapore Health Services - the largest public healthcare provider - in the Health Services Research department. She also completed a Postgraduate Certificate in Health Economics at the University of Aberdeen during her stay in Singapore. In Paris, Saskia worked as a health economist at the French National Health Insurance Company. At SiRM, Saskia is final project partner for various clients in healthcare, including healthcare providers, healthcare insurance companies, the Dutch Ministry of Health et cetera. The projects she leads are often aimed at solving complex (policy) issues, in which elements such as quality of care, financing, funding and regulation play a role.

Erik Bogsch, Biosimilar Business Unit Director, Gedeon Richter, Hungary

Dr. Erik Bogsch is the Head of the Biotechnology Business Unit at Gedeon Richter Plc (GR). The Biotechnology Business Unit covers all activities GR conducts within the biotechnology space, including development, manufacture and commercialisation of biosimilars in addition to CDMO activities. Erik has a PhD in Cell Biology and his research interests were in the area of protein transfer processes. He is the author of multiple scientific publications. Erik has worked in both the food and pharmaceutical business' in multiple geographies and has filled positions primarily in Development, but also in Manufacturing and Quality. He has been working for Gedeon Richter Plc. since 2012. As Director of the Biotechnology Business Unit he is responsible for the development, production and business strategy of biotechnology-based medicines within the Company.

Margaret Kyle, Centre for Industrial Economics (CERNA), France

Margaret Kyle (MINES Paris and CEPR) currently holds the Chair in Intellectual Property and Markets for Technology at MINES Paris. Her research concerns innovation, productivity and competition. She has a number of papers examining R&D productivity in the pharmaceutical industry, specifically the role of geographic and academic spillovers; the firm-specific and policy determinants of the diffusion of new products; generic competition; and the use of markets for technology. Recent work examines the effect of trade and IP policies on the level, location and direction of R&D investment and competition. She also works on issues of innovation and access to therapies in developing countries. Her papers have been published in various journals of economics, strategy, and health policy, including the Quarterly Journal of Economics, Review of Economics and Statistics, RAND Journal of Economics, Journal of Public Economics, Journal of Industrial Economics, Journal of Law and Economics, Antitrust Law Journal, Management Science, and Health Affairs. Margaret holds a PhD in economics from the Massachusetts Institute of Technology and is an associate editor of the International Journal of Industrial Organization. She previously held positions at Carnegie Mellon University, Duke University, London Business School, and the Toulouse School of Economics. Margaret is currently a member of the Conseil National de Productivité in France and the Economic Advisory Group on Competition Policy for the European Commission.

Julia Pike - Global Head of IP, Sandoz

Since March 2020, Julia has been the Global Head of IP for Sandoz, a leading generic and biosimilar company in the process of being spun-off from Novartis. After leaving private practice in Australia in 2002, Julia has been in-house counsel for generic pharmaceuticals including at Mayne Pharma and Hospira Inc, before joining Sandoz in 2008. In her previous roles with Sandoz, she led the global IP litigation function and was proud to be part of the first wave of US biosimilars litigation, culminating in the landmark US Supreme Court decision, Sandoz v Amgen. She has maintained a keen interest in IP strategy and litigation worldwide, including cases arising under the Hatch-Waxman and BPCIA legislation in the US, PM(NOC) regulations in Canada and litigation arising from patent linkage systems around the world. She is particularly excited about the opportunity to shape the new Sandoz IP strategy, including taking a more active role in shaping global IP policy, having started at Sandoz in European public affairs.

Alexandra Moulson, Chief Development Officer and Managing director, Polpharma Biologics

Alex is an experienced leader and strategist with a broad background in drug development, portfolio management, and commercial strategy. She has over 20 years of experience in pharmaceuticals and has worked in biosimilars since 2010. Alex is British, with Biochemistry and MBA degrees. Following her MBA, Alex spent 6 years at McKinsey leaving as an Associate Principal, 2 years at Morphosys in Business Development and joined Sandoz in 2010. At Sandoz Alex was responsible for bringing a rituximab biosimilar to the EU and Japanese markets.

She later led the Strategy Department for Sandoz. She joined Polpharma Biologics in 2019 and is currently the Chief Strategy and Portfolio Officer for the company.

Marius Geanta - Association Centre for Innovation in Medicine (Ino-Med), Romania

Marius Geantă is President and Co-Founder of the Center for Innovation in Medicine, a leading European research, innovation and policy not for profit organisation. Dr. Marius Geantă act as well as Coordinator of 4P-CAN project (Personalized CANcer Primary Prevention research through Citizen Participation and digitally enabled social innovation), Chair of Working Group Education and Curricula at International Consortium for Personalised Medicine (ICPerMed), Trustee and Chair of the Innovation and Policy Advisory Committee, FH Europe, Member of 1+ Million Genomes Member States Group representatives. As Co-Founder and President of the Centre for Innovation in Medicine, Marius Geantă is coordinator or principal investigator in multiple cancer-related innovative projects (such as 4P-CAN, ReThinkHPVaccination, PRIME-ROSE, GUIDE.MRD, National Cancer Competency Center) aiming to implement EBCP and Cancer Mission at National, Regional and European Level.

Kati Sarnola – Senior Researcher, Kela Social Insurance Institution, Finland

Dr. Kati Sarnola, Senior Researcher, PhD (Pharm), MSc (Econ), Expert in Medication Review, works in the Social Insurance Institution of Finland (Kela), the authority responsible for the implementation and payment of social security, such as, inter alia, medicine reimbursements. In Research at Kela, she is currently responsible for research concerning the use, uptake and markets of biologic medicines, while her other research interests are the uptake, lifecycle, availability and accessibility of medicines and especially novel therapies, in oncology for example. She is also responsible for the process of expert opinions on the price and reimbursement of novel outpatient care medicines to support the decision-making of the respective authority, the Pharmaceutical Pricing Board under the Ministry of Social Affairs and Health in Finland, and she has served as a member in multiple national and international steering or expert groups.
During her working career in the patient care, academia and in the Finnish Medicines Agency, prior to her currents responsibilities in the Social Insurance Institution of Finland, she has gained respective expertise in the field of pharmaceutical and health policy and economics. Her publication record covers over 130 research outputs, including scientific publications, conference proceedings, development and research reports, and articles intended for professionals or general public.

Peter Schneider - Health Economist at the Austrian National Public Health Institute (GeOG), Austria

Peter Schneider works at the Pharmacoeconomics department at the Austrian National Public Health Institute. He studied Economics and International Development at the University of Vienna, Austria. After his graduation in 2010 he received a scholarship for the Erasmus Mundus Master Programme ‘Economics of International Trade and European Integration’ (EITEI), hosted by the Staffordshire University, UK, the University of Antwerp, Belgium, and the University

of Economics in Prague, Czech Republic. He is part of the WHO Collaborating Centre on Pharmaceutical Pricing and Reimbursement Policies and is involved in the Executive Committee of EURIPID, a voluntary, non-profit collaboration of the European pricing and reimbursement authorities. In both projects he gained extensive experience in performing international price comparisons and comparing national pharmaceutical systems. In addition to this, he has been coordinating several projects in the field of pharmaceutical pricing and reimbursement policy analysis for national or international decision-makers and is author/co-author of publications in this field. From March to June 2020, he supported the test task force in the COVID-19 crisis response team of the Austrian Federal Ministry of Health. From November 2020 to May 2021 he was head of the unit which dealt with the situational oversight, publication of guidance documents and development of measures. Furthermore, he is a member of the Austrian Health Economics Association (ATHEA) and is currently finalising his PhD in the field of pharmaceutical policy analysis at the Business Administration University in Vienna. The topic of his thesis is linked to his research interests at the Pharmacoeconomics department and examines if current pharmaceutical policies in European countries are adequate for biosimilars.

Esa Heinonen - Chair of the HMA Biosimilar Working Group, Senior Adviser, Fimea

Esa Heinonen has retired from Finnish Medicines agency (Fimea) having worked there as Director of Assessment of Medicinal Products covering marketing authorizations, clinical trials and pharmacovigilance. After retirement he has, however, continued to work in some international consortia like chairing the HMA Biosimilar Working Group. During his Fimea years he became very acquainted with the development of guidelines of biosimilars having been a member of the Biosimilar Medicines Working Party (BMWP) of EMA. During his regulatory carrier he served also as the Director of marketing authorizations in the Swiss medicines agency, Swissmedic. Before the regulatory carrier he was the Director of R&D and member of the Management Board at Orion Pharma, Finland for several years.

Sanja Matić - Head of Department for Utilisation and Prices of Medicines, Agency for Medicines (Halmed), Croatia

Experienced professional with history of success in Public Administration in Health care and in global pharmaceutical sector. Active contribution to creation of policies for medicinal products at national level, at EU Commission and in World Health Organization. Well established track records of start-ups development, development of mature businesses and business model changes in pharmaceutical corporate setting. Extensive background in market access, brand management and commercial business development. **Education and credentials:**
Master of Public Health and Management in Health Care, *Medical University Zagreb, Croatia*
Master of Business and Administration, Presidents' MBA, *Bled School of Management, Slovenia*
Master of Science in Pharmacy, *University of Pharmacy, Zagreb, Croatia*

Julie Maréchal-Jamil, Director Biosimilar 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.

Kate O'Regan, Head of Communications and Stakeholder Relations, 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.

Aurelio Arias - Director, 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.

Rosa Giuliani - Medical oncologist, UK

Dr Giuliani is a consultant medical oncologist currently working at Guy's and St Thomas' NHS Foundation Trust, London, U.K. Her main interests are breast cancer, clinical and regulatory development of innovative drugs. She earned both her medical and oncology specialty degree from the University of Rome, La Sapienza. She dedicated several years specializing in the treatment of breast cancer at the MD Anderson Cancer Centre, Houston, TX (1999), at the Breast Unit of the Jules Bordet Institute in Brussels (2001-2003), at the Cancer Cell Biology Dept of Hammersmith Hospital (2005-2006) and at the Breast Unit of Charing Cross Hospital (2008) in London. Dr Giuliani was a National Expert on secondment at the European Medicine Agency, EMA, (2011-12), core member of the EMA Scientific Advisory Group in Oncology (SAG-O, April 2012-June 2021) and she is currently the co-chair of the Healthcare Professional Working party (2022-2025). She served a Member of the Executive Board and Director of Public Policy of the European Society for Medical Oncology (ESMO) from January 2020 till December 2022. In October 2023 she was awarded with the Fellow of ESMO (FESMO) title, awarded to ESMO members demonstrating exceptional commitment to the Society. She is currently in the board of Directors of the Cancer Drug Development Forum (CDDF) an in the steering committee of the European Academy Access (EAA). Dr Giuliani is the author of peer reviewed articles and she regularly lectures at international meetings.

Chiara Brouns, Policy Advisor, Dutch Healthcare Insurers, The Netherlands

Chiara works as strategic purchaser and policy advisor at Zorgverzekeraars Nederland (Association of Health Insurers for The Netherlands) leading the Clean Team that negotiates with pharmaceutical companies about prices and purchasing conditions for expensive medicines. Goal is to improve affordability of expensive medicines, lower net spending and hence contribute to access for patients and more sustainable spending on pharmaceuticals. Because of her former roles in purchasing expensive pharmaceuticals at health insurer Menzis and Erasmus MC and her background in Health Economics Chiara has seen many sides of the complex environment of pricing and reimbursement for expensive medicines.

Zorana Maravic, Chief Executive Officer, Digestive Cancers Europe (DiCE)

A part of Europacolon and now DiCE since 2012, Zorana has always worked closely with our Full Members and Associate Members. With grace, poise and calm, she is working to help Members' organisations and DiCE grow. As CEO, Zorana continues her commitment to DiCE taking on the management of the organisation and ensuring the delivery of its missions and goals. In her past role as Director of Operations she was responsible for the co-ordination and support of Member groups, as well as strengthening the network, through establishing relationships with new organisations.
During this she has proven her capacity to deliver successfully. Key projects have included:

- A Survey on the Unmet Needs of Patients Living with Metastatic Colorectal Cancer (mCRC). She recruited more than 800 patients and had the results under her authorship published widely

- DiCE events: Masterclass events – an educational annual meeting for Member groups
- Awareness campaigns including European Colorectal Cancer Awareness Campaigns (ECCAM)
- Pharmaceutical industry and independent consortia projects
- Developing patient support materials with the Patient Advisory Committee (PAC)

Zorana also acts as a public speaker on topics such as patient support, biosimilars and CRC screening. From 2016 until 2018, Zorana served as a Board Member of EuropaColon. Before working in the Not-For-Profit sector, Zorana worked for 10 years in the pharmaceutical industry, primarily in sales and marketing of innovative oncology drugs as well as on oncology clinical trials. She holds a degree in molecular biology from the University of Belgrade, Serbia. In 2017, at the University of Sheffield, UK she gained an Executive MBA in Health Management.

Elena Guillen Benitez, MD, Clinical Pharmacologist, PhD candidate

Elena is a medical doctor specialized in Clinical Pharmacology, currently working in the development of advanced therapy medicinal products (ATMP) at Hospital Clinic (Barcelona, Spain). She has broad experience in the development and assessment of biologics, biosimilars, ATMPs and innovational products. Since September 2021, she has been conducting research on the biosimilar regulatory framework across Europe, as part of the European Medicines Agency (EMA) Collaborating National Expert program and englobed in part of her doctoral thesis candidate at Universitat Autonoma Barcelona (UAB).

René Anour - Chair of EMA Biosimilar Medicines Working Party and Austrian Medicines Agency (AGES), Austria

René Anour is working as a senior clinical expert for the Austrian Federal Office for Safety in Health Care, where he is involved in centralised Marketing Authorisations and EMA Scientific Advice. He is furthermore Process Lead of National Scientific Advice at his agency. He has been a member of the EMA's Biosimilar Medicinal Products Working Party since 2020 and has been elected the Working Party's chair in 2023. He is furthermore a member of the HMA Biosimilar Working Group.

Nils Jost - Assessor, Paul Ehrlich Institute (PEI), Germany

Dr. Nils Jost is an assessor at the Paul-Ehrlich-Institute (PEI). He started in 2013 within the Innovation Office where he coordinated scientific advice meetings for advanced therapies (ATMPs). In 2014 he joined the Immunology department of the PEI where he works as a CMC and non-clinical assessor for clinical trial applications, scientific advices, EMA centralized marketing authorizations, and national marketing authorizations for mono- and polyclonal antibodies. Since 2023 he is a member of the EMA Biosimilar Working Party (BMWP) and HMA Biosimilar Working Group (BSWG).

Niklas Ekman - Vice-Chair of EMA Biosimilar Medicines Working Party, BWP Member, Head of Biological Section, Senior Researcher at Finnish Medicines Agency (FIMEA)

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 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 a member of the Biologics Working Party (BWP). He is also involved in the work of the Heads of Medicines Agencies (HMA) Biosimilar Working Group (BSWG).

Andrea Laslop, Head of Scientific Office, Principal Expert Austrian Medicines Agency (AGES), Austria

Andrea Laslop joined the Austrian Medicines and Medical Devices Agency, a business unit of the Austrian Agency for Health and Food Safety, upon its foundation on January 1st, 2006. She is the head of the Scientific Office, which constitutes the link to the European Medicines Agency (EMA) with a focus on the different types of centralised European procedures during drug development, marketing authorisation and life-cycle management. Since 2003 she is a member of the EMA Scientific Advice Working Party and from 2007 until the end of 2022 she served as delegate in the Committee for Medicinal Products for Human Use at the EMA. Prior to this Andrea Laslop worked as professor of pharmacology and toxicology at the Medical University of Innsbruck, Austria, where she had earned her degree as medical doctor with subsequent specialisation in pharmacology and toxicology.

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 for biosimilars and generic medicines at Sandoz.

Mina Grguri - Biosimilar Policy & Science Officer, Medicines for Europe

Mina is the Biosimilar Science and Policy Officer at Medicines for Europe, the trade association representing the generic, biosimilar, and value-added medicines industry. After graduating from university in her home country, Serbia, and becoming a pharmacist, Mina began her professional career in the sphere of clinical trials in a global CRO company. Joining Medicines for Europe and the healthcare policy sector at the beginning of 2023 gave her the opportunity to merge her pharmaceutical knowledge and her passion for improving healthcare outcomes with a patient centric approach. In her role, Mina has been involved in advocating for a strong EU biosimilar industry and the evolution of biosimilar regulatory framework, aiming to increase access to off-patent biologic therapies across Europe.

Ivana Knezevic, Scientist, Team leader World Health Organization (WHO)

Dr Knezevic is Specialist in Medical Microbiology and Parasitology. She received her MD from the University of Novi Sad, MSc in Medicine (Microbiology) and PhD in Medicine (Virology) from the University of Belgrade, Serbia. Dr Ivana Knezevic has 22 years of professional experience in standardization, scientific and regulatory overview of biologicals. During the first seven years, the expertise in the production, quality control and overall evaluation of vaccines and biological therapeutics was developed at the national level. Following the WHO Global Training Network on potency testing of live attenuated oral polio vaccines at the National Institute of Biological Standardization and Control (NIBSC) in the UK in 1996, she established virology laboratory for quality control of viral vaccines and interferons at the National Control Laboratory and the National Regulatory Authority in Serbia. Dr Knezevic is a Scientist at the WHO Biological Standardization Programme, where she joined in September 2000, and since then her activities have been devoted to the standardization and evaluation of biologicals at global level. Since 2006, she has been leading the team for standardization of vaccines and some biological therapeutics which consists of five scientists and three support staff in the WHO Headquarters. Main aspects of the work include development and establishment of WHO International Standards as well as providing assistance to the regulators, manufacturers and other users of these standards.

Being responsible for the development and implementation of more than 30 guidelines and recommendations to assure quality, safety and efficacy of vaccines and biotherapeutic products, Dr Knezevic has established a valuable set of scientific principles for regulatory oversight of biologicals. Among them, development of the WHO regulatory guidelines on various aspects of vaccine evaluation, i.e. cell substrates, stability, non-clinical and clinical, as well as the recommendations for production, control and evaluation of selected vaccines, e.g. polio, rabies, pertussis, pneumococcal, dengue, yellow fever, combined vaccines, published in the WHO Technical Report Series, are some of the most important projects. In the area of biotherapeutics, she coordinated the development of WHO's Guidelines on evaluation of Similar Biotherapeutic Products (SBPs), and organized a series of workshops to facilitate the implementation of guiding principles for evaluation of biotherapeutic products into regulatory and manufacturers' practice. Being responsible for eight WHO Collaborating Centers for standardization and evaluation of vaccines and other biologicals, Dr Knezevic created numerous scientific projects that involve collaborative efforts on the issues of importance for global public health. Working with more than 50 institutions in WHO member states including the national regulatory authorities, standard setting bodies, universities, manufacturers associations, and other expert groups, she developed skills for translating the science into practice, systematic review of evidence and consensus based decisions. Dr Knezevic is also the author of more than 50 publications that made broad audience aware of WHO's initiative in the development, establishment and implementation of standards for vaccines and biotherapeutic products.

Eveline Schurink, MD MPH, VP Clinical Development, Patient's Safety and Medical Affairs, Alvotech

Eveline is a medical doctor with a specialization in public health focused on health economics and management of health care systems. She has worked in the biopharma industry for more than 20 years, in Europe and in Africa, working across innovative medicines, generics and biosimilars. For almost a decade she has been working as executive board member in several African countries developing health insurance products using generics according to the WHO formulary guidelines, providing access to care to many on the continent. For the past few years, her focus has been on the development and the availability of biosimilar medicines for patients across the globe. Eveline believes that biosimilars are a great opportunity to increase treatment access for patients, thereby creating significant impact on quality of life for patients.

Dr. Jorge Mestre-Ferrandiz, Independent economics researcher and consultant

Jorge Mestre-Ferrandiz is an independent health economics researcher and consultant since 2017, based in Madrid, Spain. He spent 15 years at The Office of Health Economics, starting as an Industrial Economist and finishing as Director of Consulting. Jorge has more than 20 years' experience consulting to the life sciences industry and related non-profit organisations and his clients and collaborators have included many global top 30 pharmaceutical companies, public sector organisations, international bodies, and a range of NGOs. He specialises in the economics of the industry, the pricing and reimbursement of medicines, the impact of public policy on R&D and innovation, R&D costs of new medicines, market access, the economics of rare diseases and orphan medicines, the economics of antimicrobial resistance (AMR), and pharmaceutical product portfolios. Recently he has co-authored two technical reports for the WHO Oslo Medicines Initiative. On the economics of biosimilars in particular, his first paper dates from 2008, and has recently co-authored two papers on capturing the holistic value of biosimilars in Europe. Jorge has a PhD in Economic Analysis from the University Autonoma of Barcelona, has published over 90 papers on health economics and is regularly invited to speak on related topics at academic and commercial international conferences. He is also an Associate Senior Research Fellow at the Science Policy Research Unit (SPRU) in the University of Sussex, a Visiting Fellow at OHE, member of the Editorial Board of Applied Health Economics and Health Policy, and member of the Advisory Board of Fundación Weber and Fundació HiTT respectively.

Maja Graf - Associate Director, Policy & Market Access, Medicines for Europe

Maja Graf is an Associate Director Policy & Market Access for Medicines for Europe, a trade association representing the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value-added industries. In her role, she focuses on issues such as equitable access to affordable treatments across Europe, achieved by sustainable pharmaceutical market for off-patent medicines and innovation throughout the medicines life cycle, in the form of Value Added Medicines. She holds the Master of Sciences of Pharmacy degree obtained from Faculty of pharmacy, University of Ljubljana.

Before joining Medicines for Europe, she worked in the pharmaceutical industry. Medicines for Europe is a leading partner for better healthcare aims to increase the health and wellbeing of all Europeans through better access to high-quality medicines.
life sciences.

Magnus Bodin, Chair of the Biosimilar Market Access Committee, Medicines for Europe and Head of International Access & Policy, 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.

Pål Rydstrøm - Senior Project Manager, Sykehusinnkjøp (SHI), Norway

Education: Master's in pharmacy at University of Oslo. Position: Chief advisor at Norwegian Hospital Procurement Trust, Division Drug Procurement. Broad experience from pharmaceutical industry (1982 to 2017) covering several areas and leader positions. From 2000 also responsible for hospital tenders and negotiations with pharmacy chains in Norway. Started as Deputy advisor at Norwegian Hospital Procurement Trust in 2017. Responsibility covered among other things 9 national tenders, designing, and implementing the Pharmaceutical Strategy for tenders carried out in Norway. Member of the common Nordic tender project team and from 2020 member of the Nordic Pharmaceutical Forum. Invited at speaker by the EU Commission to Meeting of the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) to share Norwegian and Nordic experiences with biosimilar tenders and multi-switches.

Mark Samuels - British Generic Medicines Association (BGMA), United Kingdom

Mark is the Chief Executive of both British Generic Manufacturers Association (BGMA) as well as its sister body the British Biosimilars Association (BBA). Mark's career has spanned diverse experience across the life sciences sector. He is a former executive at Roche and co-founded the Medicines Discovery Catapult Ltd. He was the founding Managing Director of the government's Office for Clinical Research Infrastructure – instrumental in managing the Department of Health's £0.6 billion/year investment in research centres across the NHS.

Mark served for seven years on the Chief Medical Officer for England's strategy board for health research, and he has worked with Number 10 to contribute to the Prime Minister's strategy for

Julian Perelman – Professor, National School of Public Health of the Nova University of Lisbon, Portugal

Julian Perelman holds a PhD in Economics from Université catholique de Louvain (Belgium). He is currently full professor at Nova National School of Public Health (NOVA University of Lisbon), and Vice-President of the Portuguese Commission for Health Technology Evaluation (CATS). He coordinated the Mission Framework for the Sustainability of the Health Budget Program (Ministry of Health and Ministry of Finance), from 2018 to 2020. He authored more than 100 publications in indexed scientific journals and one book; he was the first author of the Portuguese guidelines for economic evaluation of health technologies (published in 2019). His research is mainly related to economic evaluation in health, socioeconomic determinants of health, and payment systems and incentives.

Gillian Woollett, VP, Head Regulatory Strategy and Policy, Samsung Bioepis and Biosimilars Committee Chair, IGBA

Dr. Gillian Woollett joined Samsung Bioepis in November 2021 as VP, Head Regulatory Strategy and Policy, US (SBUS), to stand up a US presence for science-based regulatory strategy and policy in the leading global market for biologics, including but not limited to biosimilars. Prior she was SVP and Principal Regulatory Scientist at Avalere Health where she led the FDA Policy and Regulatory Strategy Practice, providing the "prequel" of scientific and technical expertise to support drugs, biologics and devices gaining approval at the FDA in a manner that allows them to be commercially successful. Previously, Dr. Woollett was Chief Scientist, and Administrator, at the law firm of Engel & Novitt, LLP. She was VP, Science and Regulatory Affairs at BIO, after serving as AVP at PhRMA, where her group led on the negotiation and creation with FDA of the comparability protocol in support of manufacturing changes to already licensed biologics (that became the conceptual basis of biosimilarity). In her PhRMA capacity, she testified before Congress and represented the biopharma industry in the media as the industries' voice on international, as well as US, regulatory and scientific issues. She has served on Federal Advisory Committees; for example, as the industry representative on CDC's Board of Scientific Counsellors to the National Center for Infectious Disease. She is an appointee to the Nomenclature and Labelling Expert Committee of the United States Pharmacopeia (USP), was on the Board for the Foundation for The Accreditation of Cellular Therapy (FACT), and served on the Science Board of the Pharmaceutical Education Research Institute (PERI). Dr. Woollett earned her B.A., M.A. in Biochemistry from the University of Cambridge, and her D.Phil. in Immunology from the University of Oxford in the UK.

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.

Fabricio Carneiro de Oliveira, General Manager of Biological Products, ANVISA, Brasil

Fabrício Oliveira is a Pharmacist who graduated from the Federal University Of Minas Gerais (UFMG), Brazil and a Specialist in Health Surveillance. He started with ANVISA (National Health Surveillance Agency) in 2005 in the marketing authorizations office. From 2011 to 2013, he was an advisor in the ANVISA's Board Of Directors. In 2015 he was the manager of the Cells, Tissues, Blood, Organs Office and then moved in 2016 to the ANVISA inspectorate. Since August 2022, Fabrício has been the Head of Biological Products and Advanced Therapy Medicinal Products Office.

Rana Malkawi - Drug Directorate Director/ Regulatory Affairs Consultant, JFDA, Jordan

Rana holds a master degree in pharmaceutical quality assurance, With more than 16 years of experience in the field of Regulatory affairs, both the theoretical knowledge on legislations governing medical products & the understanding of the technicalities involved in regulatory submission. Also serving as head of clinical studies department for more than 5 years gave her experience in the field of clinical trials operations & GCP guidelines. Also she was a member of the regulatory team who collaborated in the preparation & review of the "Guidance for Registration of Biosimilars in Jordan" that was published in may/2015, also she is a well-recognized speaker in the field of Biosimilar regulations & requirements, also she has fair knowledge in Intellectual property & public health issues related to pharmaceuticals.
She started her career in the private sector then moved to JFDA in 2008, since then she has held many positions including head of new drugs registration section, head of biological and vaccine registration section, head of Clinical Studies Department, administrative assistant to director general. She chaired and was a member of many technical committees at JFDA and MOH.

Stacey Ricci – Director, Scientific Review Staff, Office of Therapeutic Biologics and Biosimilars, CDER, FDA, USA

For the past 18+ years, my work at FDA has focused on the scientific and regulatory review of therapeutic protein products. As Director of SRS, it is my honor to lead a talented and dedicated 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 by conducting regulatory science research, facilitating scientific dialogue (within FDA and through stakeholder engagement), developing and contributing to guidance and rulemaking, and providing educational and training opportunities.

Anne Cook – Expert Quality Assessor, Medicines and Healthcare products Regulatory Agency (MHRA) UK

Anne is an Expert Biologicals Quality Assessor at MHRA (UK), where she has worked for more than 19 years. She has assessed new Marketing Authorisation Applications and post-authorisation variations, predominantly for biotechnology and biosimilar products, including several biosimilar monoclonal antibodies. More recently much of the focus has been on COVID-19 vaccines and therapeutics. She also provides scientific advice to companies and academic groups developing biological products (including biosimilars). Anne has been involved in several projects to build confidence in the use of biosimilar products for healthcare professionals (www.icmra.info/drupal/sites/default/files/2019-07/ICMRA_statement_about_confidence_in_Biosimilar_product_HCP.PDF) and also for patients and the public (www.england.nhs.uk/publication/what-is-a-biosimilar-medicine/). Anne is an author on a peer-reviewed publication 'Streamlined approval of biosimilars: moving on from the confirmatory efficacy trial' (https://doi.org/10.1016/j.drudis.2020.09.006). She was involved in writing the MHRA biosimilar guidance (Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk), which was published in May 2021, following a public consultation in 2020.

Fabrice Romanet, Vice-chair, Biosimilar Medicines Group, Medicines for Europe and Head of Innovation and Development Biosimilars – Fresenius Kabi Biopharma, Managing Director Fresenius Kabi SwissBiosim

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 innovation, research and development departments Fresenius Kabi Biopharmaceuticals Business Unit with it's HQ based in Eysins, 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, 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.