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22nd REGULATORY AFFAIRS AND PHARMACOVIGILANCE CONFERENCE

THE HOTEL, BRUSSELS
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Speaker, Chair and Panellist CVs

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).

Giorgos Rossides, Head of Cabinet Stella Kyriakides, Commissioner for Health and Food Safety, European Commission

Giorgos Rossides is the Head of Cabinet for European Commissioner for Health and Food Safety, Stella Kyriakides.
From 2015-2019 he was a Member of Cabinet for the European Commissioner in charge of Migration, Home Affairs and Citizenship, Mr Dimitris Avramopoulos. He was in charge of the work on the Security Union, relations with the United States and Canada, as well as relations with the UN, NATO and the G7. Between 2010 and 2015 Giorgos served at DG Justice of the European Commission, working on the General Data Protection Regulation, and was seconded to the Presidency of the Council of the EU for the interinstitutional negotiations on data protection. He had previously worked on consumer law at the Health and Consumers Directorate-General between 2005-2010. Giorgos holds a Master's Degree in Philosophy, Politics and Economics from the University of Oxford, and a Master's Degree in International Relations and Economics from Columbia University.

Emer Cooke, Executive Director, European Medicines Agency (EMA)

Emer Cooke is as of 16 November 2020 the new Executive Director of the European Medicines Agency, based in Amsterdam. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA). She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies. Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

Karl Broich, President, BfArM (DE), Chair of the Heads of Medicines Agencies (HMA) Management Group

Prof. Broich is a physician (neurology, psychiatry, cognitive behavioural therapy) and has been President of the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn since 2014. His current activities in the European network of regulatory authorities are Member of the Management Board of the European Medicines Agency (EMA MB), Chair of the Network Portfolio Advisory Group (NPAG). He is a member of the Heads of Medicines Agencies (HMA) Management Group and is currently its Chair. He is also co-chair of the EMA's Darwin EU Advisory Board. His scientific focus is on clinical psychopharmacology, imaging of neurodegenerative diseases and other potential biomarkers and dementia, and clinical trial methodology, among others. Prof. Karl Broich is author and co-author of more than 220 papers (original scientific papers, reviews, book contributions).

Csaba Kontor, Health Attaché, Permanent Representation of Hungary to the EU

Csaba Kontor has been working as health attaché since 2015. During this period he participated at all the Council discussions in health matters (e.g. medical devices, health technology assessment, health union package and covid related dossiers). Currently he is following the discussion on the current dossiers such as regulations on European Health Dataspace and Substances of Human Origin. Besides he is in charge of the negotiations on the pharmaceutical package. Beforehand he worked in the ministry responsible for health as deputy head of the pharmaceutical department.

Philip Hines, Engagement Manager, Thought Leadership, IQVIA

Philip Hines recently joined IQVIA's Thought Leadership team, using IQVIA data and expertise to analyse EU policy and inform stakeholders. This builds on his previous role at the European Medicines Agency, working on strategic foresight to generate insights into the future of healthcare. And follows his previous years working on EU policy in Brussels as well as a PhD in evidence-informed policymaking.

Caroline Kleinjan, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz

Nationality: Dutch, University Education:
1980-1986: University of Leiden Pharmacy, Graduated as pharmacist
1987: University of Utrecht Pharmacy, Graduated as public pharmacist Working experience: 1988-1990: Pharmacist in a public pharmacy
1990-1992: QA Manager, Multipharma B.V. (now rebranded into Sandoz B.V), the Netherlands Education as QP, acting as QP for Modipack (packaging company, owned by Ciba-Geigy B.V)
1993-1994: Regulatory Affairs Manager, Multipharma B.V. (now rebranded into Sandoz B.V.) NL
1995-2004: Subsequently Technical Affairs Associate, Registration Manager and Head of the Centre for Generic Drug Registration Europe, Novartis Generics
Since 01-01-2005 Head Regulatory Competence Centre Europe, Sandoz. This department is responsible for all new submissions in geographical Europe within the Sandoz organization and subsequent maintenance of the marketing authorization till launch of the product. After launch the marketing authorization maintenance is moved to a dedicated maintenance team.

Sergio Napolitano, General Counsel and External Relations Director, Medicines for Europe

Sergio Napolitano is General Counsel and External Relations Director at Medicines for Europe. At Medicines for Europe since January 2013, in 2018 he was nominated in a list of the 50 most influential people worldwide in IP law, policy and business. Before joining Medicines for Europe, Sergio Napolitano worked in the Directorate General for External Policies of the European Parliament and at the Permanent Representation of Italy to the EU on multilateral, plurilateral and bilateral trade negotiations, EU investment policy and IPR. Sergio Napolitano holds a degree in Law from the University of Naples Suor Orsola Benincasa and a LL.M. on EU and European Public Law from the University College of London (UCL).

Florian Schmidt, Deputy Head of Unit, DG SANTE

Florian Schmidt is the deputy head of unit of the Commission's pharmaceutical unit D.1 in the Directorate-General for Health and Food Safety (DG SANTE). He is a lawyer by training and joined the Commission in 2004. Amongst other things, he was involved in the implementation of the new pharmacovigilance legislation and followed the paediatric regulation, as well as general legal matters and court cases. He is now working on the Pharmaceutical Strategy for Europe and its implementation.

Sandra Kruger-Peters, MT-member, Department of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport

Sandra Kruger-Peters is MT member in the department of Pharmaceutical Affairs and Medical Technology. Her focus is on pricing and reimbursement of medicines and on all international matters relating to medicines, medical devices and substances of human origin. Before she joined the ministry of Health, Welfare and Sport, she worked within the Medicines Evaluation Board and held different positions. She started her professional career in the pharmaceutical industry as a regulatory affairs manager. Sandra has a MSc in Biopharmaceutical Sciences and is an experienced professional in pharmaceutical legislation.

Momir Radulović, Executive Director, Slovenian Medicines and Medical Devices Agency (JAZMP), SI

Momir Radulović leads the Slovenian Medicines and Medical Devices Agency since December 2018. He is a member EMA Management Board and Heads of Medicines (HMA) Management Group, a member of EC Pharmaceutical Committee, EURIPID Board of Participants Chair and a member of EU Network Training Centre. His previous work experience includes Hospital and Community Pharmacy and Pharma industry, where his work focused on oncology medicines, HIV, vaccines and *in vitro* diagnostics. By living in 6 and working in 10 different countries with diverse health systems and cultural environments and through different work areas, projects, and assignments he has learned to adapt swiftly to changes and to seize the opportunities that those can offer.

Sarah Faircliffe, Legal Director, Bird & Bird

Sarah is a Legal Director in Bird & Bird's London office, specialising in European life sciences regulatory law. She spent 10 years as a Legal Adviser with the European Medicines Agency covering areas such as orphan drugs, paediatrics and generics of centrally authorised products, as well as advising the EMA's scientific committees on numerous legal issues. She played a key role in the project to ensure that the new EU member states joining in 2004 brought their pharma legislation and procedures into line with EU requirements. Working closely with the European Commission, she assisted with EMA-related litigation and the drafting and implementation of legislation. At Bird & Bird, Sarah uses her in-depth knowledge of the regulatory framework to assist clients on all aspects of the regulation of products in the life sciences sector. This ranges from advising on the correct interpretation of legislation, guidelines and case law to helping to steer clients through procedures and negotiations relating to the marketing of their products, including representing them in discussions with regulatory bodies and in litigation. Much of this work involves working closely with Bird & Bird colleagues in other offices to provide pan-European regulatory advice. Strategies and disputes concerning regulatory data protection and orphan exclusivity are a particular focus of her current work. Sarah is a regular speaker at conferences and workshops and contributes to a number of publications.

Stella Koukaki, Scientific Affairs Director, Managing Partner, Pharos

Stella is the founder and Managing Partner of PharOS Ltd., a company specializing for more than 20 years in product development, global registration, manufacturing and supply of generic and value-added products. Prior to that, Stella worked for other well-known pharmaceutical companies in the Generics Industry specializing in Product Development and Regulatory Affairs. Stella holds a University degree in Chemistry. She also has an MSc in Regulatory Affairs from the University of Wales. She has 25 years of experience in EU and non-EU Regulatory Affairs.

Liana Petrosova, Regulatory Policy Manager, Medicines for Europe

Liana Petrosova is a Regulatory Policy Manager at Medicines for Europe working predominantly on the topics related to manufacturing, environmental and supply chain regulations. She holds a master’s degree in public health from Maastricht University. Before joining Medicines for Europe, Liana worked on health policy research projects for EU institutions, including the European Parliament, DG SANTE, DG RTD, JRC, and ECDC. She contributed to studies on medicines shortages in the EU and on the evaluation of the EU general pharmaceutical evaluation in her previous role as a policy consultant.

Britt Vermeij, Senior Director Regulatory Policy and Intelligence Europe, TEVA

Britt studied pharmacy at the University of Utrecht in the Netherlands. In 2001, she started working for Teva in the Regulatory Affairs Department of the Dutch commercial Business Unit. From 2005 she headed this department in Teva Netherlands. In 2009 she got the position of Regional RA Head, in which she was managing Western European local RA departments in 11 countries. From 2012 on she changed to the role of European Regulatory Intelligence and Policy, which changed in April 2018 to the role of Director Regulatory Affairs Projects and Policy implementation in which she was the EU RA project lead for implementation of EU projects like Brexit, ePI and FMD. In 2022 she changed her role to Senior Director Regulatory Policy and Intelligence, in which she continues to work on ePI, assessment of new, revised or proposed legislation and providing EU Regulatory information throughout the company. For several years she is the vice-chair of Medicines for Europe Regulatory and Scientific Affairs Committee and active in several working groups.

Herta Palfi, Chair of the Regulatory Affairs Committee, Hungarian Pharmaceutical Manufacturers Association

Herta is the Chair of the Regulatory Committee of the Hungarian Pharmaceutical Manufacturers Association, Budapest. Herta graduated as a veterinarian at the University of Veterinary Sciences, Hungary, Budapest. After a few years employment as a regulatory specialist in a company manufacturing veterinary medicinal products and vaccines, Herta joined Gedeon Richter. She was the global head of the RA department being responsible for filing applications, maintenance of marketing authorisations in all geographic regions where Richter operates. She was a Member of the Regulatory and Scientific Affairs Committee, Medicines for Europe. Herta resigned her position in 2019 and currently works as a consultant. As the Chair of the Regulatory Committee Herta is delegated by the Hungarian Pharmaceutical Manufacturers Association to RSAC, Medicines for Europe. Herta is a Board member of the Hungarian Regulatory Affairs Association (since 2000 to date) and is a Joint Lecturer at the Faculty of Pharmacy, Semmelweis University.

Björn Eriksson, MD, PhD, Director General, Swedish Medicines Agency MPA (SE)

Björn Eriksson serves as Director General of the Swedish Medical Products Agency, MPA, since 2021. He has served as a member of the management board of the MPA since 2018. Earned his medical degree with a speciality in Cardiology and a PhD in Cardiology and Clinical physiology from Karolinska Institute. He has held clinical and research positions at Karolinska University hospital (1996-2005) and he has been working with clinical research in the pharmaceutical industry (2005-2010). Managerial experience includes industry and being head of clinical departments in Östersund and at Akademiska University hospital in Uppsala.

In 2013 he was appointed Regional County Director for Region Jämtland-Härjedalen and thereafter University Hospital Director for Skåne University hospital, Lund and Malmö. During the first year of SARS Covid-19 pandemia he served as Health Care Director in Stockholm. In the EU regulatory network, he is a member of the EMA Management Board and vice-chair of the HMA Management Group were he has special responsibilities for clinical trials.

Harald Mische, Deputy Head of Unit D2, DG SANTE

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.

Monica Dias, Head of Supply and Availability of medicines and medical devices, EMA

Dr. Dias is Head of supply and availability of medicines and devices, at EMA since October 2021 and she is responsible for the implementation of the extended mandate of EMA in the area of shortages of medicines and devices. She is Co-Chair of the HMA/EMA TF on Availability of Authorised Medicines (AAM) and she is the Chair of the Medicine Shortages SPOC Working Party. Dr. Monica Dias studied pharmacy in Lisbon, Portugal and obtained her PhD from the University of Cardiff, UK. Dr. Dias joined the European Medicines Agency in 2004. Dr Dias coordinated the activities of EMA in the area of shortages and availability of medicines with the setting up of the HMA/EMA TF AAM since November 2016, including Brexit preparedness activities and during the COVID-19 pandemic.

Domenico di Giorgio, Head of Inspection and Certification Department and of the Pharmaceutical Crime Counteracting Office, AIFA

Head of Inspection & Certification Department and of the Pharmaceutical Crime Counteracting Office at the Italian Medicines Agency (AIFA). Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention. He is the editor of the books "Counterfeit medicines: facts and case studies" (CoE/EDQM, 2009, 2011), The IMPACT Handbook (IMPACT/AIFA, 2011), and of the related publications series about investigators training and risk communication. He chaired the EDQM/Council of Europe Committees CMED (Counterfeit medicines) and CDPPH (Steering Committee Pharmaceuticals) dealing with pharmaceuticals products and counterfeiting, and coordinated FAKESHARE I and II (2013), projects of shared IT intelligence co-funded by the Prevention of and Fight against Crime Programme of the European Union, aimed at developing web resources for investigators dealing with pharmaceutical crime at an international level. He led the Volcano Operation, an international operation against a huge infiltration of falsified medicines in the European network, and coordinated the publication of the related White Paper for the EC.

Sophie Dagens, Regulatory Policy Officer, Medicines for Europe

Sophie Dagens is a Regulatory Policy officer at Medicines for Europe, representing the generic, biosimilar and value-added pharmaceutical industry. She works on topics including regulatory affairs, digitalisation initiatives, anti-counterfeiting, and industrial policy.

Katerina Patavou, Head of European Public Affairs & Social Impact Strategist, Panhellenic Union of Pharmaceutical Industries

Katerina Patavou is a graduate from the University of Reading with a bachelor degree in Law (LLB) and a masters in EU Law from Kings College London. With over 10 years of professional EU public affairs experience, she is an experienced consultant with a demonstrated history of working in the health and pharmaceutical industry. She finessed her business acumen during her tenure at Brussels based consultancies Burson Marsteller, DODS Europe and GPlus Europe after working as accredited assistant at the European Parliament. Since 2013, she is Head of EU Public Affairs and Social Impact Strategist for the Panhellenic Union of Pharmaceutical Industry, a national association member of Medicines for Europe representing 49 Greek pharmaceutical manufacturing companies with 45 production sites throughout Greece.

Beata Stepniewska, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe

Beata Stepniewska is Deputy Director General, Head of Regulatory Affairs of Medicines for Europe in Brussels. In this position, she is responsible for coordinating the regulatory and scientific activities, covering a variety of EU and international regulatory developments. She is also responsible for the coordination of several internal Committees and Working Groups, including the Regulatory and Scientific Affairs Committee. She is also a member of the ICH Management Committee and the ICH General Assembly on behalf of the IGBA (International Generic and Biosimilar medicines Association). Having worked with the Medicines for Europe (formerly EGA) since early 2002, Beata has been involved in expressing the position of the generic medicines industry to the European Commission, Parliament and Council as well as the CMDh, the EMA and National Competent Authorities on a number of pieces of legislation and on many regulatory guidelines related to marketing authorization. In her previous position as the Regulatory Affairs and EU Accession Manager, she was responsible for building a regulatory dialogue between the EU and authorities and industry of South East European Countries (Croatia, B&H, Serbia, Kosovo, Montenegro and Turkey) to increase the level of regulatory harmonisation between the EU and non EU countries and to facilitate operational activities of EGA members on both EU and non-EU markets. Before joining the EGA, Beata was Head of the Regulatory Affairs Department of PLIVA Krakow (currently a part of the TEVA group) and Regulatory Intelligence Manager for the PLIVA Group. Before joining the generic medicines industry, she worked as a University researcher and lecturer at the Faculty of Pharmacy in Krakow (Poland) as head of Department of Pharmaceutical Law and Pharmacoeconomics. She is a qualified pharmacist.

Kora Doorduyn-van der Stoep, Chair of the CMDh, MEB (NL)

She works at the Medicines Evaluation Board (MEB) in The Netherlands. She held several positions within the MEB, both regulatory and management. Her current position is Chairperson CMDh/EU representative at the MEB. She was acting as Member and official representative in the CMDh (Co-ordination Group Mutual Recognition and Decentralised Procedures – Human) on behalf of the MEB from May 2009 until November 2020. From December 2018 until November 2020 she also acted as Vice-Chairperson of CMDh. As CMDh chair she is also member of several EMA/HMA Task forces and other groups (like Scientific Coordination Board, EMA/HMA focus groups on resources). She is acting as CMDh rapporteur for a (HaRP) project to harmonise RMPs for the same active substance in the EU. She is coordinator/ Rapporteur EU Training Curriculum for Regulatory experts (for CMDh). She is the NL member of the Notice to Applicants Working Group in Brussels. She graduated MSc Pharmacy (in 1983) and as a pharmacist (in 1985).

Lilia Luchianov, Policy Officer, DG SANTÉ, European Commission

Lilia Luchianov, from the European Commission, DG SANTE, has been working in the area of pharmaceuticals for many years, first in DG COMP and later in DG SANTE. Today at DG SANTE Lilia deals with the revision of the pharmaceutical legislation and will be involved in the associated legislative processes. Lilia has also contributed to a handbook in the area of pharmaceuticals (EU Law of Competition and Trade in the Pharmaceutical Sector, 2019), has been a lecturer on Competition Law and Intellectual Property Law, University of Strasbourg, and delivered a great number of presentations to professional audience in the area of pharmaceutical law, competition law and IP law. Lilia is qualified lawyer and she holds an LLM in European Law from the College of Europe, Bruges, and a Master's degree in Business Law from the University of Strasbourg.

Andrew Modley, Senior Director European Generic Registrations, TEVA

Andrew as over 20 years of European regulatory experience and works for Teva as Senior Director in European Generic Registrations where he is responsible for new submissions for generic retail products.

Alexander Gehrke, Senior Manager Regulatory Affairs, Viatris

Alexander holds a Ph.D. in life sciences and has 15+ years industry experience in different companies with the majority of positions being in Regulatory Affairs. The scope of his activities covered branded& generic products, pre-/post-approval, implementation of systems/ databases& processes for regulatory purposes. He is also actively working on internal EU regulatory intelligence for the past 10y and contributing to Medicines for Europe working groups.

Anjana Pindoria-Rettenberger, Director of Product Strategy, Extedo

Anjana is the Director Product Strategy at EXTEDO. With over 15 years of experience in Regulatory Affairs and digital programs. Throughout her career, she has been responsible for various aspects, from writing MAA applications to implementing new standards such as eCTD, XEVMPD, and multiple company integration of global product acquisitions. Within Product Management, she plays a critical role in listening to industry challenges and identifying areas for innovation. Her role also involves scanning the horizon for future changes that could impact how we work today including eCTD 4.0, ePI and IDMP. She is proactively involved in ePI as a technical co-lead in the IATF.

Sara Rafael Almeida, Policy Officer, DG SANTÉ, European Commission

Sara Rafael Almeida is a Policy Officer at the Unit dealing with Medicines: policy, authorisation and monitoring at the European Commission's DG SANTE. Sara is a member of the Pharmaceutical Strategy team responsible for the evaluation and review of the pharmaceutical legislation. She is responsible for the digitisation files of the unit, including the electronic product information (ePI) initiative and the activities in the area of real world evidence. Before joining SANTE, she was a Policy Analyst at the Foresight and Behavioural Insights Unit, of the Joint Research Centre European Commission. Sara started her career in the European Commission in DG SANCO working on big data at the eHealth and Health Technology Assessment Unit. Sara studied law at Nova University Lisbon, and health economics, policy and law at Erasmus University Rotterdam.

Jasper-Hugo Brouwers, Head of Corporate and Stakeholder Affairs MEB (NL)

Jasper-Hugo Brouwers has been working at the Medicines Evaluation Board in the Netherlands for over 10 years in several roles. Currently he is the head of corporate and stakeholder affairs, including the medicines use team responsible for electronic product information (ePI). He is also chair of the Dutch Network of Patient Information. Before his time at the MEB Jasper-Hugo worked as a consultant for several medical technology and pharmaceutical companies, and holds degrees in business administration and media & communications.

Peter Bachmann, Head International Liaison Office and Conferences, European Union and International Affairs, BfArM, DE

Peter Bachmann has joint in 1999 the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of 'Drug Approval'. He was in the following years the head of several subunits and units responsible for the variation and authorisation of medicinal product in the framework of MRP, including the task of the German representative to the MRFG (Mutual Recognition Facilitation Group). Following the reorganisation of the BfArM in July 2005, Peter Bachmann was appointed as Senior Expert for 'European Drug Regulatory Affairs' at Department 'European and International Affairs'. He was the appointed German CMDh member until November 2011 and served as elected CMDh Chair from November 2011 till November 2017. His current position is the Head of 'International Liason Office and Conferences' at BfArM. He is acting as Co-Chair of the European Union Network Data Board (EU NDB), is a member of the EU Big Data Steering Group (BDSG) (since 2020), the BfArM-Scientific Coordinator of the Horizon 2020-Projekt UNICOM (2019 – 2024) and the Deputy-Lead of UNICOM WP 3. Peter Bachmann is since 2018 on behalf of the European Commission a Management Committee Member of the International Pharmaceutical Regulators Programme (IPRP) and serve from 2020 - 2023 as the elected IPRP Vice-Chair and Chair. He is also a member of the EU ICH MC Team (since 2018) and the European Lead to the ICH GDG (Generic Discussion Group).He is a lecturer for 'Drug Regulatory Affairs' at the Universities of Bonn, Duisburg-Essen, Basel and Copenhagen, a honorary member of the 'Middle-European Society for Regulatory Affairs' (MEGRA), a honorary life-time TOPRA-member, a former member and Vice-Chair of the DIA Advisory Committee Europe (2007 – 2013), DIA Board of Directors (2013 – 2016), a DIA Fellow (2021) and is currently serving as Member of the DIA Council of Regulators. He is currently acting as a Board Member of the German Society for Regulatory Affairs.

Katja Pečjak, Billev Pharma East, Industry SME for EMA ePI Pilot Project

Katja has a Master's in Pharmacy and has been in pharma industry for 20 years. Her journey in Billev Pharma East Ltd. started in September 2008, as a Director of Regulatory Affairs and EU QPPV. Presently, she is responsible for the business development within the company and empowering the team with a profound understanding of intricate pharmaceutical business processes. Her expertise has been sought when she was called upon to assume the role of Subject Matter Expert in the EMA ePI Pilot Project, representing the Pharmaceutical Industry perspective since July 2022. She is a member of Medicines for Europe working groups (RSAC, Telematics), TOPRA and an ePI Topic Group Lead in IRISS Forum. Already during 2010-2014 she was a Member of the EMA eSubmission Change Control Board from initial set up until the implementation of the new EMA Telematics governance structure. She has a history as an entrepreneur within the life science industry, spanning multiple years of experience and she has been extensively involved in business development, regulatory strategies, telematics projects and leading the pharmacovigilance system. Having cultivated a diverse background across various sectors within the life science industry, she has acquired valuable insights into the consequential effects on pharmaceutical business processes.

Zaïde Frias, Head of Digital Business Transformation Task Force, EMA

Zaïde Frias has degrees in Pharmacy and Business Administration. Prior to joining the European Medicines Agency she worked in the Pharmaceutical Industry. She joined the EMA in 1999; she was appointed Head of Human Medicines Research and Development Support Division in 2013 and Head of Head of Human Medicines Evaluation Division in 2016. In March 2020, she took the position of Head of Digital Business Transformation Task Force. The Digital Business Transformation Task Force is driving complex, disruptive change initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU medicines regulatory network, its partners and stakeholders. It operates as a hub for innovation, experimentation and collaboration, continuously taking advantage of technological innovations and emerging technologies for the ultimate benefit of public and animal health in the European Union. Within the Task Force, the Digital Innovation Lab (DigiLab) identifies opportunities and ideas for digital innovation across the Agency and to translate these into solutions to existing and emerging business needs. The Analytics Centre of Excellence (ACE) explores how data analytics - including artificial intelligence (AI), robotics and machine learning – can be used to build pragmatic solutions for existing EMA business needs. Zaide also chairs the EMA Portfolio Board and leads the Agile Transformation of the Network Portfolio.

Julian Beach, Int. Executive Director, Healthcare Quality and Access, MHRA, UK

A committed professional with over 10 years of Director level experience with a broad demonstrated history at Novartis, Pfizer and GSK in pharmaceuticals. Flexibly skilled in Quality, Health and Safety, Operations with passion for people development with results and improvement focus. Quickly adaptable with strong links to industry and regulatory bodies with country, scientific, commercial and business focuses. Working with industry and regulators to influence legislation to benefit both patients and business. A Fellow of the RSC, with an MBA from Henley Business School, adding to BSc (Hons), Chartered Chemist and Chartered Scientist.