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24th Regulatory Affairs CONFERENCE

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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 of the European Medicines Verification Organization (EMVO) board for the implementation of serialization against falsified medicines, the International Generic and Biosimilar medicines Association (IGBA) and the joint industry advisory council of the Health Emergency and Response Authority (HERA).

Olga Solomon - Head of Unit for Medicines: Policy, Authorisation and Monitoring - Directorate General for Health and Food Safety (SANTE), European Commission (TBC)

I hold a degree in Chemistry from the University of Thessaloniki and a Master's degree in Food Science from the University of Gothenburg. My professional journey has shaped my expertise in various domains. Following my five-year experience at a prominent beverage company in Greece, I joined the European Commission in 2001. Over two decades, I gained experience in the field of food safety, in areas such as food additives, enzymes, and food contact materials and in the past 12 years in the area of pharmaceuticals. Since May 2017, I am Head of Unit SANTE D.1 'Medicines: policy, authorisation, and monitoring' and have taken up the role of acting Director in SANTE D: 'Medical products and Innovation' since March 2023. My professional journey has equipped me with extensive knowledge and skills in health policies, risk assessment, management and communication. Throughout my career, I have navigated complex stakeholder landscapes and negotiated with the European Parliament and the Council on proposals related to food and pharmaceuticals. In close collaboration with Member States and European Agencies, such as the European Food Safety Authority and the European Medicines Agency, I have fostered fruitful partnerships. Beyond the European stage, my influence has extended to international forums. Notably, I successfully negotiated food standards within the Codex Alimentarius and spearheaded activities pertaining to bilateral and multilateral relations with global partners in the pharmaceutical field. I have guided my team through preparedness and crisis management activities during crucial events such as Brexit and the COVID-19 pandemic, including the expedited authorisation of vaccines and therapeutics. One of my notable achievements lies in my pivotal role in

shaping the Pharmaceutical Strategy for Europe. Moreover, I led the implementation of this strategy, including the adoption in April 2023 of a comprehensive package of proposals for the revision of the pharmaceutical legislation.

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

Emer Cooke has been the Executive Director of the European Medicines Agency, based in Amsterdam, since November 2020. She served as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for five years, from the beginning of her EMA mandate until the end of October 2025. Between November 2016 and November 2020, she was the Director responsible for all medical product related regulatory activities at the World Health Organization in Geneva. Ms Cooke is a pharmacist with Master's degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and held management positions at the EMA as Head of Inspections and Head of International Affairs respectively from 2002 until 2016. Between 1998 and 2002 she worked in the Pharmaceuticals unit of the European Commission, where intra-alia, she was responsible for international collaboration, EU enlargement and the orphan medicines regulation. Prior to this, Ms Cooke worked at the European Federation of Pharmaceutical industries and Associations (EFPIA) (1992–1998), in the Czech Republic as an independent pharmaceutical policy advisor (1996–1998) and in the Irish pharmaceutical sector (1985–1990). Starting her mandate as EMA's Executive Director in November 2020 amid a public health crisis of unprecedented scale she announced "My number one priority will be to drive forward EMA's response to the pandemic and the work already ongoing to support the development and approval of safe and effective COVID-19 vaccines and treatments." Doing precisely that, has earned her various awards including the 'European of the Year 2022' award by European Movement Ireland and Honorary Doctorates in Science (Royal College of Surgeons in Ireland – 2023 and National University of Ireland - 2025).

Rui Santos Ivo - President, INFARMED (PT), Chair of the EMA Management Board (TBC)

Rui Santos Ivo is currently President of INFARMED – National Authority of Medicines and Health Products, I.P. (since July 2019), and Invited Associate Professor at the Faculty of Pharmacy of the University of Lisbon in the area of Medicines Regulation (since 2009). At European level, he is member of the Management Board of the European Medicines Agency (EMA) since 2016 and vice-chair since October 2024, and Chair of the Heads of Health Technology Assessment Agencies Group (HAG) (since September 2021). He is also a member of the Heads of Agencies Management Group (HMA-MG) and currently is one of the co-leads of the European Medicines Agencies Network Strategy. Over the years, at the Ministry of Health in Portugal, he held various positions, including: President (2002-2005) and Vice-President of INFARMED (1994-2000; 2016-2019) and President (2014-2016) and Vice-President (2011-2014) of the Central Administration of the Health System, a public institute responsible for the planning and management of the financial, healthcare provision and human resources of the National Health System (NHS). He gathered relevant international experience in the area of medicines' regulation and health technologies, namely as Administrator at the Directorate of EMA in London (2000-2002) and in the exercise of executive functions in the Pharmaceutical Unit of the Directorate-General for Enterprise and Industry in Brussels (2006-2008). He was the first Chairman of the European Union Heads of Medicines Agencies Management Group (2004-2005). Between 2008 and

2011, he was Executive Director of the Portuguese Association of the Pharmaceutical Industry (APIFARMA). Rui Santos Ivo began his professional career as a hospital pharmacist at the Egas Moniz Hospital in Lisbon (now part of the West Lisbon Local Health Unit) and in 1993 joined INFARMED, where he began working in the Licensing and Inspection Department. Graduated in Pharmaceutical Sciences from the University of Lisbon in 1987. Specialist in Hospital Pharmacy by the Ministry of Health (1992) and the Pharmaceutical Society (2006) and in Pharmaceutical Regulation, honorary, by the Portuguese Pharmaceutical Society (1997). Postgraduate education on Health Law and Pharmaceutical Legislation (by the University of Lisbon Faculty of Law and National School of Public Health, 1997), Pharmaceutical Medicine (by the University of Basel, 1999), Regulation (by the London School of Economics and Political Science, 1999) and on Health Management (by the Portuguese Catholic University, 2000, and by AESE Business School, 2015). In April 2004, he was awarded the Almofariz "Personality of the Year" Award (2004) in the pharmaceutical sector. In 2014 he was appointed European Correspondent Member of the Académie de Pharmacie, France. In 2015 he received the Gold Medal for Distinct Services by the Ministry of Health. In 2023 he received in the hands of the Portuguese President of the Republic the insignia of Honorary Member of the Order of Merit, awarded to INFARMED, I.P. In 2024 he was distinguished by the Council of the College of Speciality in Hospital Pharmacy of the Portuguese Pharmaceutical Society with a Career Award (Prémio Pegadas) and with the Lifetime Achievement Award by TOPRA – The Organisation for Professionals in Regulatory Affairs.

María Jesús Lamas Díaz - Director, Spanish Agency for Medicines and Medical Devices (AEMPS)

María Jesús Lamas, Director of the Spanish Agency for Medicines and Medical Devices (AEMPS) since 2018.
She holds a PhD in pharmacy about pharmacogenomics in cancer and certifications in oncology clinical pharmacy.
María also holds a prominent leadership role in European health regulation as Chair of the Management Group of the Heads of Medicines Agencies (HMA) and as Spain's representative on the Management Board of HERA. She is a member of several high-level governance and advisory bodies, including the EMA Management Board, the MSSG, MDSSG, and the ACT-EU Steering Group. María co-chairs the Multistakeholder Platform Advisory Group, chairs the EU-IN group, and is a member of HAG. Her work has played an important role in shaping the regulatory science, innovation, and competitiveness agenda under the EMANS 2028 strategy.

Member of the HMA Task Force on horizontal legislations (TBN)

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

University Education: 1980-1986: University of Leiden Pharmacy, graduated as pharmacist **I** 1987: University of Utrecht Pharmacy, graduated as public pharmacist. Working experience: 1988-1990: Pharmacist in a public pharmacy **I** 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) **I** 1993-1994: Regulatory Affairs Manager, Multipharma B.V. (now rebranded into Sandoz B.V.) NL **I** 1995-2004: Subsequently Technical Affairs Associate, Registration Manager and Head of the Centre for Generic Drug Registration Europe, Novartis Generics **I** Since 01-10-2023 Head Regulatory Europe, Sandoz. Leading all country regulatory organisations in Region Europe and the teams that are responsible for the execution of all the new submissions and prelaunch regulatory activities in geographical Europe.

Juan García Burgos - Head of Public and Stakeholders Engagement Department, EMA

Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences. In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.

Beatriz Solanas - Digital Regulatory Policy Officer, Medicines for Europe

Razvan Prisada - President, ANM (RO) (TBC)

National Pharmacist Association Representative (TBN)

Patient/Consumer Representative (TBN)

Britt Vermeij - Vice-Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Senior Director Regulatory Policy & Intelligence EU, 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.

Katja Pečjak-Reven, 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.

Anjana Pindoria-Rettenberger - Director of Product Strategy, Extedo, a cormeo brand

Anjana is a passionate advocate for patient empowerment. With over 20 years of experience in the Pharmaceutical and Global Health Authority sector, she possesses strategic insights into the medicinal product journey, from pharma development to patient care. As the Director of Product Strategy at EXTEDO, Anjana actively listening to industry challenges, identifying areas for innovation, and spearheading transformative initiatives within the global network. Anjana's expertise extends beyond the present; she scans the horizon for future changes that could impact our work today. Her niche experience positions her as a strategic expert for organizations striving to stay ahead of industry trends and regulatory developments.

Stella Koukaki - Partner, PharOs Ltd.

Stella is the founder and Partner of PharOS Ltd., a company specializing in product development, manufacturing, global registration and supply of generic 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.

Hélène Bruguera - Head of the Certification of Substances Division, EDQM

Quality WP member (topic lead) and/ or the NCA ASMF assessor (TBN)

Karina Boszko - Head of Global Regulatory Affairs and Customer Technical Service, Polpharma

Nino Mihokovic - Pharmaceutical Quality Specialist, EMA (TBC)

Hilde Vanneste - Director CMC Regulatory Affairs, Johnson & Johnson on behalf of APIC

Ellen Nieuwenhuijse - Head Corporate Affairs, Sandoz

Beata Stepniewska - Executive Director Regulatory and Scientific Affairs, Medicines for Europe

Beata Stepniewska is Executive Director Regulatory and Scientific 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.

Christina Kougia - Legal Manager, PharOs

Andrew Modley - Senior Director, European Generic Registrations and Maintenance, 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.

DG SANTE, European Commission (TBN)

Laurence O'Dwyer - International and Policy Manager, HPRA (IE)

Laurence is a pharmacist who joined the Health Products Regulatory Authority (HPRA) in 2004. Having worked for many years as a quality assessor for medicines, in 2016 he was appointed as Scientific Affairs Manager which included responsibility for the HPRA's Innovation Office. Since 2020 he has co-chaired the EU-Innovation Network, which brings together representatives from innovation offices in national competent authorities and the EMA's Innovation Task Force. Last year he took up a new role as the HPRA's International and Policy Manager, as part of which he has played a lead role within the HPRA on the revision of the EU pharmaceutical legislation.

Dovile Marcinke - Executive Director, LRV (LT) (TBC)

Liana Petrosova - Senior Regulatory Operations Policy Manager, Medicines for Europe

Liana Petrosova is a Senior Regulatory Policy Manager at Medicines for Europe, leading the organization's engagement on medicine shortages, sustainable manufacturing, and regulatory compliance. She works to ensure that European pharmaceutical policies reflect the realities of the pharmaceutical value chain for generic, biosimilar, and value-added medicines, improving patient access across the EU. Previously, she was a Public Policy Consultant at Technopolis Group, contributing to major European Commission studies on pharmaceutical regulation, supply chain resilience, and medicine shortages. She holds a Master's degree in Governance and Leadership in European Public Health from Maastricht University.

Laura Marrero, Spanish Agency for Medicines and Medical Devices, AEMPS, ES (TBC)

CHESSMEN WP 5 (TBC)

Brendan Cuddy - Lead Scientific Officer, Quality and Safety of Medicines Department, European Medicines Agency

Brendan Cuddy is a Lead Scientific Officer in the Quality and Safety of Medicines Department at the European Medicines Agency (EMA), where he has served since October 2002. His career spans leadership roles in manufacturing quality, inspection coordination, and supply chain integrity, including managing large multidisciplinary teams at EMA. He was Head of the Manufacturing and Quality Compliance Service at the Agency from 2014 – 2020. Since 2017, he is the Chairman of the Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG), contributing to the development and harmonisation of standards across the European Union and internationally. Brendan holds a degree in Chemistry and a postgraduate diploma in Pharmaceutical Manufacturing Technology from Trinity College Dublin, which satisfies the educational requirements of Qualified Person (QP). He also holds a Master's degree in Quality and Operations Management from the National University of Ireland, Galway.

Herta Palfine, MAGYOSZ

MAH supply speaker (TBN)

Phyllida Duncan - Chair of the Variations Working Group Medicines for Europe, Associate Director Regulatory Affairs Policy Europe, Sandoz

Phyllida graduated from Victoria University of Wellington in 2016 with a Bachelor of Biomedical Science with first class honours. After graduation she took on the role of Science and Technical Advisor for national trade association Medicines New Zealand where she analysed the local regulatory and market access environment and advocated for reducing barriers to medicine access. In 2020 she joined Sandoz' Regulatory Europe department located in The Netherlands where she managed initial marketing authorisation applications and variations for their generic portfolio. In addition, she supported various regulatory initiatives including the EU multilingual labelling pilot. Since 2024 Phyllida is part of Sandoz' dedicated Regulatory Policy function. Her focus area is regulatory policy for generic medicines in Europe. In 2025 she became the Chair of the Medicines for Europe Variations Working Group.

Susanne Winterscheid - Chair of the joint CMDh/CMDv Working Party on Variation Regulations< BfArM (DE)

Susanne is biologist and started at the BfArM in the variation section after a few years of employment in pharmaceutical industry. Since 2005 she was heading the Project Management of a licensing division at BfArM. Since 2008 she is Chair of the Joint CMD working party for variations. In November 2011 she has become the German member of the CMDh. Since June 2015 she is Head of Licensing Division 3 at BfArM. In December 2020 she was elected as Vice-Chairperson of CMDh.

Thomas Girard - Head of Regulatory Affairs Office, EMA (TBC)

Lília Bandeira - Director Global Regulatory Affairs Pharma/CMC, Pharma & Nutrition, Fresenius Kabi Pharma Portugal Lda

Lília Bandeira is a senior regulatory affairs professional with comprehensive experience in pharmaceutical development, global NDA strategy, and lifecycle management. She leads initiatives that ensure compliance while encouraging innovation across diverse international markets, overseeing the development, registration, and maintenance of a robust portfolio of pharmaceutical products. Lília holds a degree in Pharmaceutical Sciences from the University of Coimbra. She began her career in 1997 in the Quality Control and R&D Department of a national pharmaceutical company, where she honed her technical expertise. She later transitioned to regulatory affairs within a leading generics company, specializing in a wide range of pharmaceutical forms with a primary focus on injectables. Following the acquisition of this company by Fresenius Kabi in 2005, Lília joined the global regulatory affairs department, where she has played an important role in driving regulatory excellence and ensuring successful market access. Lília has contributed to securing approvals in Europe, and global markets. She actively participates in regulatory initiatives, including the Medicines for Europe variations group, reflecting her dedication to promoting collaboration and advancing best practices within the pharmaceutical sector.

Catherine Oleggini - Senior Manager, Regulatory Affairs, Viatris

Catherine Oleggini brings over 18 years of expertise in regulatory affairs across the human pharmaceutical and veterinary sectors. With a strong academic background in analytical and medicinal chemistry, she has extensive experience managing innovative and generic pharmaceutical drugs, biologicals, OTC products, pesticides, and dietary supplements in both European and global markets. She joined Mylan/Viatris in 2018 and in her current role as Senior Manager, Catherine leads a team responsible for Marketing Authorisation Applications and life-cycle management across the EEA and UK. She actively contributes to internal working groups focused on key areas such as Centralised Procedures and nitrosamines, as well as regulatory intelligence initiatives. Catherine is also a member of the Variations Working Group within Medicines for Europe.

Remco Munnik - Owner and Founder, Arcana Consultancy (TBI)

Remco Munnik has more than 25 years experience in Life Science and Regulatory Affairs, including more than a decade providing consultancy around Regulatory Information Management (RIM) and electronic submissions. He is a respected subject matter expert in RIM, eCTD, xEVMPD and ISO IDMP. Remco is Chair of Medicines for Europe Telematics group; and Vice-President of the IRISS Forum, a global, open, multidisciplinary, non-profit networking organisation for life science professionals by life science professionals. Remco supports companies in paving the way to digital healthcare, by supporting standardisation and ensuring the right technology, systems and processes are in place to enable insightful business decision-making and innovation.

Virginia Rojo Guerra - Head of Procedures Office, EMA

Karin Gröndahl - Business Development Manager, Swedish Medical Products Agency (MPA)

Karin has extensive regulatory experience at the MPA, including roles as Pharmaceutical Assessor for biological and biotechnological products and as Head of Registration and Information Management. She currently focuses on digital driven business development and portfolio management. Karin has played a key role in the EU implementation of eSubmission and the eCTD format, contributing to the drafting of the HMA eSubmission Roadmap. She is an active member of the eSubmission Expert Group, the Regulatory Optimisation Group (ROG) and the ROG PMS Operational Group, and is engaged in initiatives related to SPOR, IDMP, new electronic formats and the EU-common IT portfolio planning from a business perspective.

Georg Neuwirther - Head of IT, AGES, (AT)

Georg Neuwirther joined the Agency for Food and Health Safety (AGES) in 2003 where he held several management positions in IT and infrastructure. In 2014 he was appointed Head of IT of the division “Austrian Medicines and Medical Devices Agency” after successfully modernizing the IT landscape. He is actively involved in initiatives of the European Medicines Regulatory Network, chairs the Electronic Application (eAF) Maintenance Group, is member of the European Network Databoard (EUNDB) and was member of the EU Telematics Management Board (EUTMB), Telematics Architecture Board (TEAB), SPOR Taskforce.

Javier Monvoisin - Global Head of Regulatory Operations, Sandoz

Javier Monvoisin has over 20 years’ experience in the pharmaceutical industry having held positions in Quality, Regulatory Affairs and Regulatory Operations. He is currently Vice President of Regulatory Operations at Teva where he is responsible for implementation and support of all RA systems and processes. Javier is a subject matter expert for xEVMPD, ISO IDMP and eCTD submissions and has extensive experience in process design and implantation of RIM solutions. He was part of the xEVMPD working group and has been part of the Medicines for Europe Telematics Working Group for many years.

Aimad Torqui - Deputy Director, Medicines Evaluation Board (MEB)

Aimad Torqui is deputy director and division head at the Medicines Evaluation Board (MEB), serving on the executive management team since 2022. In this capacity, he leads national and European policy initiatives, regulatory science efforts. His responsibilities also extend to veterinary medicines and initiatives aimed at improving the use of medicines. At the European level Aimad serves as vice-chair of the Management Board of the EMA and serves on the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products MSSG. He is a co-opted member of the HMA Management Group, strategic advisor to the joint HMA/EMA Regulatory Optimisation Group, observer to the Network Data Steering Group, and serves on the Network Portfolio Advisory Group. With nearly 20 years of experience in regulatory affairs, Aimad has held roles in both government and industry. He joined the MEB in 2006, initially as a regulatory case manager, before transitioning into various roles. In 2010, he was appointed as the alternate member to CMDh. From 2013, Aimad worked in the pharmaceutical industry, where he gained experience as a regulatory affairs manager and later as a regional lead for global regulatory policy. Aimad holds degrees in biotechnology from HAN University of Applied Sciences and molecular biology from Radboud University Nijmegen.

Marta Marcelino - Chair of the CMDh, INFARMED (PT)

Tamás Parapatics - Head of Department for Pharmaceutical Strategy, NNGYK (HU) (TBC)

Zaïde Frias - Chief Digital Officer, European Medicines Agency

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. Zaïde also chairs the EMA Portfolio Board and leads the Agile Transformation of the Network Portfolio.

Tomaz Kobe - Global Head of Technology - Regulatory & Patients Safety, Sandoz

Laurance Proust - Regional Digital Marketing, Innovation & AI Transformation Lead for Europe, Viatris

Balázs Lázár - Head of Global Regulatory CMC & Operation, Gedeon Richter

Balázs Lázár is an experienced regulatory affairs professional with more than 20 years of experience in the pharmaceutical industry. He graduated as a pharmacist from Semmelweis University in Budapest in 2004 and shortly thereafter joined Gedeon Richter, a leading mid-sized European pharmaceutical company headquartered in Budapest. Over the course of his career, Balázs has held a series of progressively senior roles in regulatory affairs. He began with responsibility for regulatory activities and subsequently led a department for over a decade focused on obtaining new marketing authorizations across the European Union. He later advanced to the role of Head of Global Regulatory Operations, where he was responsible for managing worldwide regulatory operations across all phases of the product life cycle. Since 2022, Balázs has served as Head of Global Regulatory CMC & Operations, combining leadership of global regulatory operations with responsibility for CMC regulatory writing and related functions. In addition to his corporate role, Balázs is actively engaged in the regulatory community. He is a member of the Regulatory & Scientific Affairs Committee (RSAC) of Medicines for Europe, participating in several working groups. He is also a member of MAGYOSZ, the Hungarian Pharmaceutical Association, and HURAS, the Hungarian Regulatory Affairs Society. Furthermore, he is a regular invited lecturer at Semmelweis University, where he contributes to the education of future regulatory and pharmaceutical professionals.

Michiel Stam - Management Consultant, MAIN5

Michiel Stam is a Management Consultant and Regulatory Team Lead at MAIN5, with over 15 years of experience in the pharmaceutical industry and deep expertise in Regulatory Information Management (RIM) and the integration of regulatory data with enterprise systems. He has extensive hands-on experience in IDMP and EMA SPOR initiatives, helping organizations achieve sustainable regulatory data quality. Michiel has led the definition and implementation of data governance frameworks and successfully managed vendor selections and implementation projects for RIM systems. By aligning people, processes, and technology, he ensures efficient, compliant, and future-ready regulatory operations. Passionate about semantic technology and knowledge graphs, Michiel leverages innovative approaches to improve interoperability, data standardization, and automation in regulatory processes.

Hilmar Hamann - Head of Information Management Division, EMA

Dr Hilmar Hamann is the Head of Information Management at the European Medicines Agency (EMA), where he leads strategic initiatives to advance technology and digital transformation across the EU Regulatory Medicines Agencies Network with the aim to drive efficient, data-driven operations within the EU/EEA regulatory landscape.
Previously, Dr Hamann served as Director of Business Informatics at the FDA's Center for Drug Evaluation and Research (2011–2020), overseeing advancements in regulatory data management, analytics, and the modernisation of business applications to support evolving legislative and user fee requirements.