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 former 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) and the Vice-Chair of the Critical Medicines Alliance.

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.

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 also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA). 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. She has also 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 for the European Pharmaceutical Industry Association (EFPIA) and in various industry and regulatory positions in Ireland. In 2021 she received the Muckross (her alma mater) Woman of the Year award. In 2022 she received European Movement Ireland's "European of the Year" award. In 2023 she was awarded an honorary doctorate by the Royal College of Surgeons Ireland (RCSI) University of Medicines and Health Sciences.

María Jesús Lamas Díaz - Executive Director of the Spanish Agency for Medicines and Medical Devices (AEMPS), Chair of the Heads of Agencies Management Group

María Jesús Lamas Díaz is executive director of the Spanish Agency for Medicines and Medical Devices (AEMPS) since 2018 and, as such, she is responsible for its direction, management, and coordination of actions. She is also a member of the network of Heads of European medicine agencies (HMA) and the Management Board of the European Medicines Agency (EMA). Furthermore, she is the representative of Spain in the HERA Board (European Health Emergency Preparedness and Response Authority), and it should be noted that she represents Spain on the Steering Board of the European Vaccine Strategy led by the European Commission. She is a member also of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and its equivalent in Medical Devices (MDSSG), both aimed to prevent and manage the shortages of medicines and medical devices, respectively. In the field of health technology assessments, she is a member of the Heads of HTA Agencies Group (HAG). She leads several working groups within the regulatory network. She got a Ph.D. in Pharmacogenetics from the University of Santiago de Compostela, she is a clinical specialist in hospital pharmacy and holds a certificate in clinical oncology pharmacy from the Board of Pharmaceutical Specialties (BPS) and the American Pharmaceutical Association (APhA). Until she took over the direction of the AEMPS, she was the head of the Pharmacy department at the University Hospital in Santiago de Compostela. During her clinical career, she funded her research Group on Pharmacology at the Health Research Institute (IDIS – ISCIII), where she also coordinated the Platforms and Methodology Area. Formerly, she was Director of Research at the learned Spanish Society of Hospital Pharmacy (SEFH) from 2012 to 2016.

Rui Santos Ivo – President, INFARMED (PT)

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.

Marcin Kołakowski - Vice President of the Office for Registration of Medicinal Products Medical Devices and Biocidal Products

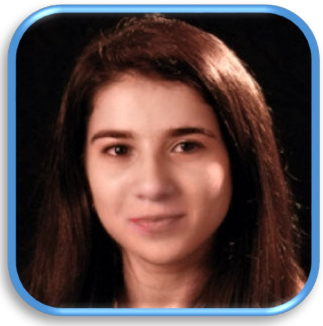
Marcin Kołakowski is the Vice President for Medicinal Products at the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products in Poland. With over two decades of experience in pharmaceutical regulation, he oversees pharmacovigilance, medicinal product registration, clinical trial supervision, and cooperation with the European Medicines Agency and the European Commission.

Previously, he served as Head of the Supervision Department at the Main Pharmaceutical Inspectorate. He holds an MBA from Warsaw University, a Master of Science in Pharmacy from the Warsaw Medical Academy, and postgraduate degrees in Industrial Pharmacy and Pharmaceutical Marketing. He is an active contributor to international regulatory initiatives and has represented Poland at the UN Commission on Narcotic Drugs.

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.



Liana Petrosova – Senior Regulatory 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.

Laure Geslin - DG Sante, European Commission

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

Joao Ferreira - Medicines and Medical Devices Shortages Specialist, European Medicines Agency (EMA)

Joao Ferreira is a Pharmacist by training, and currently a Shortages Specialist at the European Medicines Agency (EMA). Since 2021, he has been part of EMA's Supply and Availability Office, dealing with shortages and availability of medicines in Europe. He's been responsible for implementing the EMA's new extended mandate in medicine shortages. Joao is the EMA Project Lead for delivering and maintaining the "Union list of critical medicines" within the European Medicines Regulatory Network. Currently, he's also acting as EMA Project manager for implementing the HTA Regulation (HTAR), where he's responsible for planning and ensuring the delivery of the related implementing activities at EMA. He joined the EMA in 2014 and has 12+ years of experience in EU medicines regulation, safety monitoring, and transparency, as well as in policy and crisis management. Before joining the EMA, he worked in the Industry sector (in the field of) Regulatory Affairs and Pharmacovigilance consultancy.

Ellen Mc Grath, Medicine Shortages and Borderline Classification (MSBC) Manager

Ellen Mc Grath is a graduate of the University of East Anglia School of Pharmacy UK. Ellen completed her pharmacy training and worked as a resident pharmacist in Leeds Teaching Hospitals (LTH) and during this time also completed a Diploma in Clinical Pharmacy with the University of Leeds. Ellen has amassed 15 years' experience both in clinical and corporate roles. Prior to commencing as the MSBC Manager within the Compliance Department of the HPRA, Ellen's most recent role was Head of the Corporate Pharmaceutical Unit, which is the interface between the Health Service Executive (HSE) and pharmaceutical industry in relation to medicines pricing and reimbursement at a national

level. As head of the unit Ellen was responsible for all commercial negotiations for new medicines reimbursed by the HSE and also supported the State negotiation team to bring forward two 4-year national pricing Framework Agreements (IPHA 2021 Agreement and MFI 2021 Agreement). Ellen led the first of its kind negotiations in two successful pilot projects under the 'Beneluxa initiative', an international collaboration set up with an aim of providing sustainable access to innovative medicines at affordable costs for patients through joint assessment and joint decision-making on applications for reimbursement. Ellen possesses a Masters in Health Policy from Imperial College London, completing her research dissertation examining the factors influencing the outcomes of negotiated reimbursement decisions for new medicines in Ireland.

Jana Bošanská - Head of Regulatory Strategy and Policy - Europe

Jana currently holds the position of Head of Regulatory Strategy and Policy – Europe for Viatris. Jana brings 20 years' experience within pharmaceutical industry with the focus on Regulatory Affairs and Portfolio. In her current role she oversees the regulatory strategies for new MAAs across European markets and leads strategic initiatives to navigate evolving regulatory frameworks. Jana is a member of Medicines for Europe RSAC working group. She holds doctor's degree in pharmacy from Comenius University in Slovakia. She is based in Switzerland.

David Jauch, Vice President Governmental Affairs & Public Policy, Fresenius

David M. Jauch is responsible for Government Affairs and Public Policy at Fresenius. In the past he held positions of Market Access, Government Affairs and Corporate Social Responsibility (CSR) at Fresenius Kabi. He is the Chair of the Public Affairs Group, Member of the Board of Medicines for Europe as well as a member of the Trade Committee of IGBA (International Generics and Biosimilar Association) and has been working in the pharmaceutical industry for more than 10 years. David studied Business Administration at the University of Stuttgart in Germany, Tongji University in Shanghai, China and Seoul National University in Korea and holds an Executive master's in business management of Leeds University Business School in the UK.

Remco Munnik - Chair of Telematics Working Group, Medicines for Europe, Deloitte

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.

Runa Hauksdottir Hvannberg – Executive Director, Islandic Medicines Agency

As Executive Director of the Icelandic Medicines Agency (IMA) since February 2015, she leads a national agency responsible for ensuring the quality, safety, and efficacy of pharmaceuticals and medical devices in Iceland. With nearly 20 years of expertise in pharmaceutical regulation, surveillance, and pricing and reimbursement at a governmental level, Runa brings a wealth of knowledge to shaping pharmaceutical policies and strategies. Prior to joining the IMA, she chaired the Icelandic Medicine Pricing and Reimbursement Committee (IMPRC), where she played a pivotal role in national policy and pricing strategies. Her background spans academia and industry, including lecturing in pharmacoeconomics at the University of Iceland long with roles in marketing and sales management in the pharmaceutical industry, and pharmacy practice in the UK. She is actively involved in European pharmaceutical networks, contributing to collaborative projects that drive regulatory optimization and policy reform. As Chair of the Regulatory Optimisation Group (ROG), a sub-group under the Heads of Medicines Agencies (HMA) and European Medicines Agency. She lead “Sustainability of the Network and operational excellence” that is one of the six focus areas in the European medicines agencies network strategy to 2028 that focused on enhancing regulatory efficiency within the European Medicines Network. She also participates in European, Nordic, and national steering committees, aligning with the European Medicines Agency (EMA) and the European Commission to promote harmonized regulatory practices. Recently remominated HMA representative of the Network Portfolio Advisory Group (NPAG) for EMA and HMA, observer member of the EMA Management Board (EMA MB), member of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) European Medicines Agency. Throughout her career, she has contributed to various healthcare reform groups and has worked closely with international networks, such as the Network of Competent Authorities for Pricing and Reimbursement (NCAPR) and the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (PPRI). Her academic background includes an MS in Health Economics and a pharmacy degree from the University of Iceland, and an MSc in BioPharmacy from King’s College London, equipping her with a robust foun-dation in both clinical and economic aspects of pharmaceutical science.

Marcos Fernández Gómez - PMS Product Owners, EMA

Bachelor's degree in biotechnology from the University of Leon, Spain.
Regulatory Affairs manager – e-Submissions, IDMP and RIM Specialist as a consultant for 5 years
Master Data Manager – PMS co-product owner and XEVMPD business lead at EMA since 2020.

Veronica Lipucci Di Paola - PMS Product Owners, EMA

Veronica Lipucci Di Paola has been a member of the European Medicines Agency (EMA) since 2014, holding various roles throughout her tenure. She holds a Master's in Regulatory Affairs from TOPRA & the University of Hertfordshire, as well as a pharmacy degree. With over 10 years of experience in data management, Veronica specializes in Medicines for Human Use, particularly in pharmacovigilance and regulatory affairs. As the PMS Product Owner, she is responsible for delivering, coordinating, and maintaining the Product Management Services (PMS), while also leading the implementation of ISO IDMP standards across Europe. She collaborates closely with colleagues in business and development teams, as well as with stakeholders in industry and network groups. Veronica is a nominated expert in the EDQM Standard Terms Working Party and a member of the ISO IDMP group. Prior to joining the EMA, she worked as a pharmaceutical consultant and at the regional pharmacovigilance hospital center.

Anjana Pindoria-Rettenberger - Director of Product Strategy, Extedo

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.

Christopher Fordham - Packaging Technology and Artwork Manager, Accord Healthcare

I lead Packaging Technology for Accord Healthcare and led the project to implement the EU Falsified Medicines Directive across our network of packaging sites, warehouses, and commercial units. I've worked in the generics industry for 20 years, mostly focussing on packaging but with a period transferring manufacturing processes and analytical methods between our facilities. I've been Accord's lead for ePIL for around three years and I'm active in our Trade Association relationships with the BGMA and Medicines for Europe. I focus on design of robust systems to create and maintain relationships between Supply Chain and Regulatory data in the GxP environment, avoiding unnecessary complexity and risk. Fascinated by the prospect of integrating multiple, often disparate data sets and systems, and the opportunities and necessities for this which ePI brings.

Javier Monvoisin - Vice President of Regulatory Operations, TEVA

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.

Nora Weitbrecht - Senior Manager and Team Lead in Global RA Reg. Operations, Owner Regulatory Databases and IDMP Topic Owner, Sandoz

With a chemist´s diploma and a Ph.D. in Chemical Engineering in the background, Nora brings over 20 years' experience in Regulatory Affairs with a focus on world-wide maintenance and new submissions activities. For nearly 15 years now, she contributes with increasing responsibilities to the enhancement of the IT system landscape within the Sandoz RA department. She is business owner of the global RA databases at Sandoz and leads the implementation and operational processes related to external digital solutions and initiatives, like xEVMPD, SPOR, eAF, ePI, PMS, eCTD. Beginning of 2015 Nora joined the Medicines for Europe Telematics working group, and 2016 became a member of the Medicines for Europe delegation for the IDMP Task Force group. Since December 2022 she holds the mandate to represent industry as subject matter expert in the PMS product team with EMA and the European network.

Dr. Fakhredin Sayed Tabatabaei – Medicines Evaluation Board (MEB)

Fakhredin Sayed Tabatabaei is a medical doctor and an epidemiologist. He is working as Senior Assessor Pharmacovigilance at the Dutch national agency (MEB) for more than 18 years. Currently, he acts as Subject Matter Expert of the PMS (Product Management Service) development project, and member of the PMS Operational Group. He is also the chairman of the CMDh HaRP (Harmonization of Risk Management Plan) project. Fakhredin was an active member of the European ePI (electronic Product Information) Pioneer Group drafting the ePI Key Principles that is published in 2020, and still participates in the Gravitate Health project as the MEB representative.

Raluca Radu - Senior Manager, Pharmaceutical Policy

Raluca works currently as Senior Manager, Pharmaceutical Policy at Medicines for Europe. In her current role she combines her scientific background from her training as a pharmacist, with her passion for health and regulatory policy. In her daily work Raluca focuses on advocating for policies which create a supportive environment for innovation in the off-patent space, allowing us to capitalise on the full potential of existing medicines, and shift to a more sustainable drug development pathway.

Luis Pinheiro - Senior Epidemiology Expert, EMA

Luis Correia Pinheiro is a Senior Epidemiology Lead at the Data Analytics and Methods Taskforce at the European Medicines Agency. He coordinates the Health Data Lab, is part of the leadership team of the European Specialised Expert Community Special Interest Area on AI and is a co-lead for the Guidance, Policy and Product support pillar of the Heads of Medicines Agency / European Medicines Agency multi-annual AI Workplan.

Gabriel Westman MPASE - Representative of the Methodology WP

Gabriel Westman is an infectious disease specialist and associate professor (MD, PhD), member of EMA/HMA Big Data Steering Group and EMA Methodology Working Party. He also has an MSc in Engineering with experience in bioinformatics, AI and big data applications within medicine and pharmaceutics and is currently building regulatory AI/data science capacity and competence at the Swedish Medical Products Agency, exploring use of real-world data, and hoping for a better and data-driven world.

Volodymyr Stus - Head of Clinical Excellence Team, Zakłady Farmaceutyczne, Polpharma S.A.

Volodymyr Stus has a diverse work experience spanning several industries. Volodymyr is currently working at Polpharma as the Head of the Clinical Excellence Team in the Medical Department since April 2022. Prior to this, they held various roles in the same company, including Manager Biopharmaceutics and Clinical Trials in the R&D Department from January 2019 to March 2022. Before joining Polpharma, Volodymyr worked at PRA International as a Clinical Research Associate from October 2011 to October 2013. In this role, they were responsible for monitoring clinical research sites, managing site records, and providing logistics assistance. Volodymyr also gained experience at Pfizer as a Clinical Research Site Manager from February 2009 to September 2011. Volodymyr'srole involved overseeing clinical research sites and ensuring the smooth running of studies. Earlier in their career, Volodymyr worked at Farmasoft-CT as a CRSM from February 2009 to March 2011, where they monitored clinical research sites and participated in various studies. Volodymyr also held roles at TechnoPark Corp., including Sales Director from November 2007 to June 2008, Sales Manager from May 2007 to November 2007, and E-lancer from April 2007 to May 2007. Here, they gained experience in sales management and account management. In addition, Volodymyr briefly worked at Microsoft as a PAM in 2008 & at Med-Service Group as a Pharmacist/ Apothecary/Consulting Doctor from July 2005 to June 2007. Overall, Volodymyr Stus has a strong background in clinical research, sales, and pharmaceuticals, with demonstrated expertise in various roles within the industry.
Volodymyr Stus completed their education at Dnepropetrovsk Medical Lyceum from 1997 to 1999, where they received a degree as a junior nurse in the field of medicine. Volodymyr then pursued their MD degree in surgery at Dnipropetrovs'ka Deržavna Medicna Akademija from 1999 to 2005.

Mohamed Ali Kotal – Head Medical Safety, Sandoz

Physician by qualification, sportsman at heart, and PV professional by accident who is passionate about building and leading global high performing teams. Expertise in building and expanding PV systems and processes, among others ICSR, Risk Management, Signal Evaluation, Aggregate Analysis, with a high sense of duty towards patients and building trust with health authorities and physicians. In my free time I love to fulfil my duties as a loving husband and a doting father to 2 beautiful kids."

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.

Phyllida Duncan - 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 the EU, Switzerland and UK. In addition, she supported various regulatory initiatives including the EU multilingual labelling pilot, and post-Brexit UK regulatory strategy. Since 2024 Phyllida is part of Sandoz' dedicated Regulatory Policy function. Her focus area is regulatory policy for generic medicines in Europe.

Susanne Winterscheid - Chair of the joint CMDh/CMDv Working Party on Variation Regulations

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 and member of the EU Variation Task Force. 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

After having worked during 7 years in pharmaceutical industry where he held various Regulatory Affairs positions, Thomas joined the European in 2009. Within this capacity he provided regulatory intelligence and procedural advice throughout the medicinal products lifecycle, in particular on paediatrics, data protection, health threats and emerging use. He was appointed Head of Referrals Office in 2017 and Head of Regulatory Affairs Office in 2020 in the Human medicines Division. He is a Pharmacist with a Master degree in health law from Paris IX University of Paris.

Lilia Bandeira - Senior Manager, Regulatory Affairs – Pharma Europe, Asia Pacific & International, 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.

Alberto Ganan Jimenez - Head of Committees and Quality Assurance Department, EMA

Alberto Ganan Jimenez is a pharmacist and a biochemist and holds a PhD on molecular and cell Biology from University of Zaragoza (Spain). After working in pharmaceutical industry in Business Intelligence positions, Alberto joined the EMA in 2006 as a Product Lead in the Quality of Medicines Office dealing with biological medicinal products and combination products. From 2014 until 2019, he led the Procedures office responsible for the validation center and the management of minor variations and administrative procures (CPPs and parallel distribution notices). He currently works as the Head of Committees and Quality Assurance Department. This Departments hosts the secretariat of the EMA Scientific Committees, the Regulatory Affairs office, the Labeling office, the Procedures office and the secretariat of the expert panels on high-risk medical devices.

Britt Vermeij - Vice-Chair of the Regulatory and Scientific Affairs Committee Medicines for 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.

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.

Monica Buch - Senior Labelling Specialist, EMA

Monica is a Senior Labelling Specialist at the European Medicines Agency (EMA). She's been part of the Labelling team and the QRD Secretariat since she joined the Agency in 2002, initially in the Regulatory Affairs and Medical Information Sectors, and currently in the Quality Assurance Department within the Human Medicines Division. In addition to her role as labelling review specialist of the Oncology products portfolio, she is the lead of QRD activities and tasks, coordinating the QRD Plenary meetings and Industry Interested Party meetings with the QRD Group, and being responsible for the maintenance of the QRD templates and QRD reference documents and guidance for the product information of centralised human medicines. Throughout her career at the Agency, Monica has always been involved in the development of electronic product information, formerly as a member of the PIM Project Core Team, and currently as the EMA Subject Matter Expert in the ePI Project.

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.

Evinn Drusys - Member state representative participated in the ePI pilot and NCA network product owner, NCA network PL, E-labeling developer at the Spanish Agency for Medicines and Health Products (AEMPS)

Evinn studied information systems at Niagara University and the University of Sydney. He joined the Spanish medicines regulatory agency (AEMPS) in 2019 where he is currently dedicated to developing electronic product information (ePI). Since 2022 Evinn has been working alongside EMA as the NCA network product owner for the ePI project. Evinn is also a member of the Gravitate Health project which is aiming to develop a patient centric mobile app to help patients better adhere to medicines.

Dominique Westphal - PEI, (DE) - member of the QRD

Dominique Westphal joined the Paul-Ehrlich-Institute in 1999 as an assessor for medicinal products authorized via centralized procedures focusing on regulatory affairs and product information (SmPC, Labelling and PL). The Paul-Ehrlich-Institute is a federal Agency in Germany and its research and control activities promote the quality, efficacy and safety of vaccines and biomedicines. It reports to the Federal Ministry of Health. She has been Expert of the Paul-Ehrlich-Institute in Langen subsequently and assisted two former CHMP co-opted members of the PEI, BPWP-Chairperson, BWP-Vice-Chairperson and VWP-Member during their nomination periods. She has been member of various European, national and international working groups. With regard to the European Medicines Agency her current activities in the European network are member of three associated Working groups of the Committee for Medicinal Products for Human Use (NRG, QRD and SmPC advisory Group). She has contributed to sub-groups and guidelines.

Momir Radulovic - 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 Vice-Chair, a member of EC Pharmaceutical Committee, EURIPID Board of Participants Chair and a CoChair 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.

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, ROG). 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 graduated MSc Pharmacy (in 1983) and as a pharmacist (in 1985).

Aimad Torqui – Division Head Medicines Evaluation Board (MEB)

Aimad Torqui is the 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. Additionally, Aimad serves as the Netherlands' alternate member on the EMA Management Board and is a member of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). With over 15 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.

Andrew Modley - Senior Director European Generic Registrations, TEVA

Andrew works for Teva and is based in Harlow in the UK. He joined the organisation in December 2006 and has over 20 years of regulatory experience. In his current role as a Senior Director in the European regulatory affairs team he has overall regulatory ownership of obtaining and maintaining all generic Marketing Authorisations across Europe. Prior to this Andrew worked as a pharmaceutical assessor at the MHRA, and held other regulatory roles in the pharmaceutical industry.