Session 1 - Access, availability and shortages are central to Pharma Strategy: How will regulatory reforms deliver?

24 January 2022, 14.30 - 16.00 CET

Adrian van den Hoven, Director General, Medicines for Europe

Adrian van den Hoven joined Medicines for Europe as a Director General in September 2013. His priorities at Medicines for Europe are to stimulate competition in off-patent medicine markets, to foster market access for generic, biosimilar and value added medicines, to support policy measures for sustainable pricing, to promote high regulatory standards while ensuring that the associated costs can be integrated into market dynamics and to develop a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value added medicines industries. Prior to joining Medicines for Europe, Adrian van den Hoven was Deputy-Director General of BUSINESSEUROPE where he was responsible for the International Relations department, covering trade negotiations and bilateral relations, and the Industry department, covering industrial, energy, environmental and research policy. He previously worked as an International Relations researcher and an adjunct professor in Italy (EUI), France (Nice) and Canada (Windsor). He obtained his doctorate in Political Science from the University of Nice, France in 2000

Sylvain Giraud, Head of Unit - Medical products, DG Health and Food Safety, European Commission

Sylvain Giraud is the Head of Unit "Medical products: quality, safety and innovation" in the Directorate General for Health and Food Safety of the European Commission (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, the implementation of the Pharmaceutical Strategy for Europe and the coordination of international cooperation on medicines policy. In previous Head of Unit positions in DG SANTE in the last 10 years Sylvain has been dealing with Health Systems, global health and EU health policy coordination.

Momir Radulović, Head of the Slovenian Medicines Agency (JAZMP)

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, a member of Oslo Medicines Initiative Scientific Committee 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 and vaccines. 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.

Jakub Velík, Head of a Unit Expert Activity Coordination Department, State Institute for Drugs Control (SUKL), CZ

Dr. Velik is the head of the Expert Activity Coordination Department. The focus of this department is monitoring, evaluation and mitigation of the availability of medicinal products in the Czech Republic. In his work he utilises currently available data provided by MAHs, distributors and pharmacies as the mandatory reporting's and participates in proposals for legislative changes to further improve functionality of whole system ensuring optimal availability of treatment for Czech patients. In the area of not available treatments and medicines, the department is responsible for making treatment available in exceptional cases, such as individual drug imports or compassionate use programs. In its work, it closely cooperates with the registration department and, if necessary, initiates the acceleration of regulatory processes to ensure treatment. The department proposing positive and negative interventions in the re-export of medicines, and if it is necessary from the point of view of ensuring availability, it proposes appropriate restrictions to the Ministry of Health. During the COVID outbreak, Dr. Velik were involved in the preparation of national treatments guidelines and participated in the definition and monitoring of essential drugs for the treatment of patients with COVID-19. Dr. Velik is a member of Joint HMA/EMA Task Force on Availability of Authorised Medicines and is active SPOC contact person nominated by NCA Czech Republic. As he is aware of international context of shortage and availability issue, which is not connected only to COVID-19 outbreak, and he is interested to become more involved in those international activities that could contribute to the desired harmonization of the approach to shortage management within the EU. Dr. Velik was member of several working or ad hoc group where utilize his

knowledge of current approaches to shortages management at both national and international level, experience in the field of drug trade, purchasing, and procurement, knowledge of the ICU area and ability to create and interpret data analysis and demand forecasts.

Kaisa Immonen, Director of Policy, European Patients' Forum (EPF)

Kaisa Immonen (MA) is Director of Policy at the European Patients' Forum (EPF). She has a Master's degree in International Relations (UK and Finland) and is currently studying at Maastricht University for a Master's in health policy, innovation and management. Kaisa is responsible for the overall lead of EPF's policy and advocacy work at EU level, strategic planning, policy analysis, and building positive relationships with EU institutions, international organisations such as the OECD, WHO and stakeholders. Her personal interests include patients' empowerment and involvement in improving patient safety and quality of care, health literacy and health equity. Kaisa is the current co-chair of the European Medicines Agency's Patients and Consumers Working Party since 2016, a patient representative on the EMA's COVID-19 task force, represents EPF on the OECD's health care quality and outcomes working party, and is a member of the CIOMS working group XI on patient involvement. In her personal capacity she is a member of the BMJ Patient Panel and has worked with ICHOM. Before joining EPF in 2010 she worked in EU health policy, advocacy and external communications roles in both the private and non-profit sectors.

Thyra de Jongh, Principal Consultant, Technopolis

Thyra de Jongh is a Principal Consultant at Technopolis Group, with over 18 years of experience in research and consulting. Her main areas of expertise are pharmaceutical innovation and access to medicine, health systems and policy analysis and global health. She has performed studies in the area of pharmaceutical regulation and innovation for the European Commission, UNITAID, national ministries, non-governmental organisations and professional associations. She was the project leader for the study on medicine shortages in the EU and previously led the study to support the evaluation of the EU Orphan Regulation. She currently is a technical advisor to the Austrian Federal Ministry of Health and Women's Affairs to support strengthening of the pharmaceutical value chain and improve access to medicine. She holds Master degrees in Chemistry and International Health Management, and a PhD in Biochemistry.

Rebecca Guntern, President of Medicines for Europe, Sandoz

Rebecca Guntern, President of Medicines for Europe, Sandoz Rebecca joined Sandoz as Head of Sales in 2007 and has spent the last thirteen years in leadership roles. In January 2020 she took over the role as Head Sandoz Europe. Prior she led one Cluster within the Region Europe incl. the countries UK, NL, CH, Iberia, Baltics & Israel - and before the BACH countries Belgium, Austria & Switzerland. Previously she was Country Head for Spain, Cyprus and Switzerland. Before joining Sandoz Rebecca worked for Bähler Apotheken as Deputy Head & Group Project Manager, for Merck Sharp & Dohme as Marketing & Sales Manager and for Roche Pharma as Clinical Research & Sales Representative. Rebecca joined the Executive Committee of Medicines for Europe in June 2019 as vice-president of the association and takes a leading role in shaping the accessibility and affordability of off-patent medicines, with a strong focus on biosimilars. Currently Rebecca is also serving as President of Medicines for Europe ad interim. Rebecca Guntern received her Master degree in pharmacy at the University of Basel. She is a Member of the Board of Pharmasuisse, Swiss/American “Young Leaders Group”, Sciencesindustries, Société Suisse des Explosifs, Berner Kernkraftwerke and Medicines for Europe.

Erick Tyssier, Head of Government Affairs Europe, TEVA

Erick Tyssier has more than 15 years of experience in healthcare & life science policy and corporate advocacy, leading public affairs missions in the healthcare sector. He joined TEVA in 2013, to establish the European Government Affairs function handling Teva’s relationships with the EU institutions and coordinating policy and advocacy at national level, as well as Teva Europe ESG agenda. Previously he worked at Sanofi in several commercial related positions in Asia and in France before moving to Brussels in 2005. Erick is a Doctor in pharmacy, and has 2 master degrees: one in Regulatory Affairs and one in pharmaco-economics.

Session 2 - The future of generic competition and how to leverage global convergence

26 January 2022, 14.30 - 16.30 CET

Gerald Beuerle, Chair of the Bioequivalence WG Medicines for Europe, Teva

Dr. Gerald Beuerle studied pharmacy at the Julius-Maximilians-University in Würzburg, Germany and got his PhD at the Eberhard-Karls-University of Tübingen. He has been working for ratiopharm GmbH since 1996. Once ratiopharm was acquired by Teva in 2010 he became responsible for Teva Europe as Regional Manager in the Generics Global Biopharmaceutics group. After two years working in early clinical development for New Therapeutic Entities, he is now Senior Director Pharmacokinetics Europe / International Markets in the Teva Global Generics Clinical R&D organisation. Being the chair of the Bioequivalence and Clinical Development Working Group of Medicines for Europe and a member of the Steering Committee of the European Federation for Pharmaceutical Sciences (EUFEPS) Network "Bioavailability and Biopharmaceutics" he is involved considerably in discussions related to pharmacokinetic aspects and on new bioequivalence guidelines. He was speaker at several Medicines for Europe / EGA, EUFEPS and Informa meetings and a member of Organising Committees, e.g. in all four conferences related to the Global Bioequivalence Harmonization Initiative.

Sarah Ibrahim, FDA

Sarah Ibrahim is the Associate Director for Generic Drug Global Affairs in the Office of Generic Drugs (OGD)/ Center of Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In this role, Dr. Ibrahim develops OGD strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in

Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she has years of experience in the US pharmaceutical industry in the area of pharmaceutical development. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

Kevin Blake, Scientific Officer Clinical Pharmacology Scientific Evidence Generation Department, EMA

Kevin Blake is the Scientific Specialist Clinical Pharmacology in the Translational Science Office at EMA and has been Scientific Secretariat for the Pharmacokinetics Working Party (PKWP) since 2015. He is also an EMA Scientific Coordinator in the Scientific Advice Office with a focus on procedures relating to generics/hybrids. Prior to joining EMA in 2010 he was a Clinical Assessor at the then Irish Medicines Board (now HPRA) since 2006. Dr. Blake received his primary medical degree (MB. BCh. BAO) at University College Dublin in 1989 and a Ph.D. in Epidemiology at the University of Western Australia in 2003 as an Australian NHMRC scholar on the topic of fetal growth and cardiovascular disease risk in later life (the 'fetal origins' hypothesis). While at EMA he has been involved in a number of guidelines including those on post-authorisation efficacy studies (2016), first-in-human clinical trials (2017) and on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation (2018). He is also EMA lead in the development of product-specific bioequivalence guidelines with the PKWP. He has over 30 scientific publications including recent overviews of the EMA experience with PBPK models, product specific guidelines and biowaivers. His interests include the regulatory approval of generics, including complex generics; sharing regulator's experience with submitted applications; and the use of modelling and simulation/extrapolation in drug approval.

Nilufer Tampal, FDA

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in OB within OGD. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides leadership and expertise in utilization of advanced analytic data tools in the assessment of bioequivalence studies submitted in ANDAs.

Dr. Tampal serves as the FDA Topic Lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. She also served as the Rapporteur for the ICH Generic Drug Discussion Group. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance and has held various leadership positions in OB for the last 12 years. Prior to her FDA career, she gained years of experience in synthesis and analysis of small molecules working as chemist at a multinational pharmaceutical company in India.

Vincenzo Salvatore, Bonelli Erede

Vincenzo Salvatore is full Professor of European Union Law at the University of Insubria – Varese (Italy), where he teaches EU law and International Trade Law. He is also a qualified lawyer (admitted to the bar since 1991) and he practices as of counsel at BonelliErede law firm in Milan where is he the leader of the firm's Healthcare and Life Sciences Focus Team. Professor Salvatore served for eight years as Head of the Legal Service and Data Protection Officer at the European Medicines Agency (EMA) from 16 November 2004 until 15 June 2012. He is an experienced litigator and routinely represents pharma and medical devices companies before higher Courts in Italy and the Court of Justice of the European Union in Luxembourg in landmark EU law disputes. He is member of the editorial board of European Pharmaceutical Law Review.

Jim Polli, University of Maryland

Dr. James E. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. He has served as advisor to 21 Ph.D. graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each an FDA-funded collaborative agreement with the Agency. He is Director of the online MS in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience). He is a fellow of the American Association for Pharmaceutical Scientists. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB).

Susana Almeida, Clinical Development and Safety Director, Medicines for Europe, Brussels, Belgium

Dr. Susana Almeida is Clinical Development and Safety Director at Medicines for Europe (formerly EGA). Before joining Medicines for Europe, Susana was the Chair of the Association's Bioequivalence Working Group for almost 15 years. She has worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations. She has overseen the conduction of dozens of clinical trials carried out in Europe, North and South America and Asia. At Medicines for Europe, Susana is responsible for the coordination of multiple working groups, working on different aspects involving policy and regulatory science: Susana coordinates the activities related to clinical development, pharmacovigilance/drug safety, and medical devices (single integral products, Medical Device Regulation article 117). She has represented the International Generic and Biosimilar Medicines Association (IGBA) in multiple Expert Working Groups at the International Council for Harmonisation (ICH): M13, Generic Discussion Group and M9. She is also involved in the Therapeutics Pillar of the Access to COVID-19 Tools (ACT) Accelerator partnership, launched by WHO and partners. She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain and has authored several scientific papers and patents.

Session 3 - Upgrading Marketing Authorisation procedures to increase availability and tackle shortages and supply chain resilience

31 January 2022, 14.30 - 16.30 CET

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.

Beata Stepniewska, Deputy Director General, 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.

Susanne Winterscheid, German CMDh representative, 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 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.

Christelle Bouygues, Regulatory Affairs Senior Officer, EMA

Regulatory Affairs Senior Officer at the European Medicines Agency. The EMA Regulatory Affairs Office is responsible for providing regulatory intelligence and advice in relation to the development, evaluation and surveillance of medicinal products for human use submitted through the Centralised Procedure (including scientific advice, orphan, paediatric, SME) and to its Committees. I was involved in particular with the

implementation of the paediatric and pharmacovigilance legislation and I am currently coordinating the implementation of the MDR/IVDR within EMA. Before joining the Agency, I gained a 4-year experience at the French Competent Authority, in the Mutual Recognition Procedures and the Oncology Evaluation services, and had a 2-year experience in the pharmaceutical industry.

Laura Galatti, Italian CMDh representative, AIFA, IT

Laura is pharmacist (degree in Pharmaceutical Chemistry) with a post-degree specialisation in Pharmacology. After a contract as consultant for ISMETT, since 2010 she is quality assessor at the Italian Medicines Agency, involved in both variation and new application assessment. Since 2016 she is member of the Working Group on Active Substance Master File Procedures. Since 2019 she is the Italian member of the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh).

Stella Koukaki, Director Scientific Affairs and Managing Partner PharOs

Stella is the founder and Managing Partner of PharOS Ltd., a company specializing in product development, 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.

Herta Pálfi Goóts, Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ)

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 at Phylaxia-Sanofi, Budapest, a company manufacturing veterinary medicinal products and vaccines, Herta joined Gedeon Richter, Department of Regulatory Affairs, as a unit head responsible for new submissions in the European Union. Since 2001 Herta was the global head of the RA department being responsible for all regulatory activities in the company, as for supporting product development, 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 (formerly the European Generic Association). Having worked for 25 years in Richter, 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.

Birgit Ziegler, Head of Regulatory CMC, Global Regulatory Affairs, STADA Arzneimittel AG

1999: Doctoral degree; Technical University Dresden, Germany, Institute of Analytical Chemistry
Since 09/2001: Employment at European Regulatory Affairs of STADA R&D GmbH/ STADA Arzneimittel AG with different functions (Manager Regulatory Affairs/ Teamleader Own Developed Products) with the following tasks: preparation and submission of new marketing authorisation applications (MAA's) and maintenance activities, regulatory support for generic developments, preparation and submission of scientific advices for submission at National Competent Authorities, preparation of regulatory strategies.
Since 01/2012: Head of Regulatory CMC at the (Global) Regulatory Affairs Division at STADA Arzneimittel AG
The department is responsible for the preparation of Module 3 documents and Quality Overall Summaries for all markets for new MAA's and during maintenance as well as for the support of internal and external partners during development and ongoing procedures.

Jonathan Rousell, Vice President Regulatory Affairs, Europe and International Markets TEVA Pharmaceuticals

In his current role at Teva Pharmaceuticals as Vice President, Regulatory Affairs, Europe and International Markets, Jonathan leads a dedicated team of regulatory professionals that support Teva's extensive generic and OTC portfolio. His team includes a variety of regulatory strategy and submission experts, as well as labelling and CMC specialists. Working closely with R&D and commercial operations, his role supports end to end regulatory activities that cover the complete life cycle of a product. Jonathan has 20 years of experience in regulatory affairs, having moved to industry in 2001. Prior to that Jonathan gained his PhD at Imperial College and conducted post-doctoral research at both Imperial and University College London. Jonathan has a degree in Biochemistry from Leeds University.

Session 4 - Delivering on global patient safety in pharmacovigilance

2 February 2022, 14.30 - 16.30 CET

Sebastian Horn, Chair PV Working Group Medicines for Europe, Teva

Dr. Sebastian Horn is Global Head Patient Safety and Pharmacovigilance at Teva since January 2021. He has more than 20 years of experience in Patient Safety & Pharmacovigilance, including being Head Patient Safety & QPPV at Sandoz for 10 years, Head Patient Safety Medicinal Products & Medical Devices at Fresenius Kabi, Head Global Cases Processing & Safety Affiliates at Roche, Sr Medical Advisor at Boehringer Ingelheim, Safety Physician at Pfizer Germany. He was also a member of the CIOMS VIII Signal Detection working group. Sebastian is a licensed physician in Germany, and specialized in Legal Medicine before joining Pharma Industry.

Viola Macolic Sarinic, Scientific adviser on safety of medicines PRAC Scientific Committee Lead Pharmacovigilance Office Quality and Safety of Medicines Department, EMA

Viola Macolic Sarinic is a medical doctor, clinical pharmacologist by specialisation who holds a PhD in Pharmacogenomics applied to Biosciences and a master's in Clinical pharmacology (pharmacokinetics). She has more than 20 years' experience as a clinical pharmacologist and pharmacovigilance specialist, both in university hospital and in the medicines regulatory authority in Croatia working at the positions of a clinical and pharmacovigilance assessor, head of the pharmacovigilance department, national PRAC and CHMP member and served for four years as the director of the Croatian medicines agency (HALMED). Viola worked as a national expert on secondment at the EMA in London in the scientific advice office and in the WHO headquarters in Geneva, Switzerland in the Pharmacovigilance team strengthening pharmacovigilance activities within the medicines regulatory systems in low and middle income (LMIC) countries.

Now working at the EMA in Amsterdam in the position of the PRAC Scientific Committee Lead and Scientific adviser on safety of medicines in the Pharmacovigilance office.

Howard Chazin, FDA

Howard Chazin, MD, MBA, is Director of the Division of Clinical Safety and Surveillance in the Office of Safety and Clinical Evaluation within the Office of Generic Drugs (OGD) in CDER. Dr. Chazin leads several teams of physicians, nurses, pharmacists and data analysts tasked with identifying, assessing and addressing newly identified safety signals related to potentially inferior generic drug product quality, therapeutic equivalence or adverse events. He is OGD's signatory authority for Newly Identified Safety Signals and Risk Evaluation and Mitigation Strategies and facilitates postmarketing safety process improvements. Dr. Chazin received his MD from the Rutgers-Robert Wood Johnson Medical School and his Master of Business Administration in Medical Services Management from the Johns Hopkins University Carey Business School.

Pilar Bonilla, Safety Risk Management Manager Sandoz/Novartis Global Drug Development

Pilar holds a master's degree in microbiology and joined Sandoz/Novartis in 2014 as a talented excellence trainee. Her international career has already spanned three different countries in functions such pharmacovigilance, regulatory affairs, and quality assurance. Her participation at 21st Regulatory Affairs and Pharmacovigilance Virtual Conference is intended to show with real examples how global pharmacovigilance impacts the day to day operations and the challenges the pharmaceutical industry faces to implement regulatory actions.

Vicki Edwards, Vice President Pharmacovigilance Excellence and QPPV, Abbvie

Qualified as a pharmacist in 1981 and started her career in hospital pharmacy. In 1983 she specialised in Drug Information Services and moved to Kuwait to set up and run the first National Drug Information Centre. On her return to the UK, Vicki spent the next four years in community pharmacy. In 1996 Vicki joined Glaxo Wellcome and started her career in pharmacovigilance. In 2002 she moved to AstraZeneca UK Ltd as the Drug Safety Manager moving on to become Head of Drug Safety & Medical Information. Vicki joined Abbott in 2005 as European Qualified Person for Pharmacovigilance (EU QPPV). In 2013 moved to AbbVie as EU QPPV and Head of Affiliate Safety Excellence (ASE) and is now VP, Pharmacovigilance Excellence and QPPV. In addition to fulfilling EU QPPV role she is responsible for the Office of the QPPV, also a team of regionally based PV experts who oversee PV at the Affiliate level, a team who oversee AbbVie Organised Data Collection activities relative to PV, and a team responsible for maintenance and performance of the global PV QMS.

Klaudija Marijanović Barać, Sr Director, Global Patient Safety & PV (TPC), Teva

Klaudija Marijanovic Barac is a physician with almost 20 years of experience in pharmacovigilance, based in Zagreb, Croatia. Klaudija also holds post-graduate diploma in Pharmaceutical Medicine from Medical School, Free University of Brussels. She started working in pharmaceutical industry in 2002, being one of the founders of Pharmacovigilance Department in PLIVA. After acquisitions she was Lead Safety Physician in Barr Group and established RMP Group in Teva in 2015. She also led in-house development of additional risk minimisation implementation tracking tool. At present she is Senior Director within Teva Periodic reports and risk management Centre (TPC). Her team is supporting marketing authorizations worldwide for generics, innovative, biological and biosimilar products. Klaudija is co-chair of the Pharmacovigilance Working Group within Medicines for Europe.

Session 5 - Mobilising the digital opportunity to achieve interoperability in the EU medicines agency network

3 February 2022, 14.30 - 16.00 CET

Remco Munnik, Chair of the Telematics Working Group at Medicines for Europe, Iperion

+20 years in experience in Life Science and Regulatory Affairs, 10+ years consultancy with focus on Regulatory Information Management (RIM) and electronic submissions.

- Strategy & Project manager
- Subject Matter Expert for Regulatory Information Management systems (RIM), eCTD, xEVMPD and ISO IDMP
- Member of EMA ISO IDMP Task Force Organizations and Products
- Chair Medicines for Europe Telematics group (eAF, eCTD, CESP, xEVMPD and ISO IDMP)

Sabrina Conti, Policy and Regulatory Operations Manager, Medicines for Europe

Sabrina Conti is Policy and Regulatory Operations Manager at Medicines for Europe. In her role she leads the Manufacturing and Supply chain Committee, Digital and Telematics working groups, Quality and Environment groups. She is passionate about digitalisation of Health systems, operational excellence, interoperability and ePI. She is also member of the Regulatory and Scientific Affairs Committee within Medicines for Europe and coordinator of several industry inter-associations groups, such as SPOR – IDMP Steering group and electronic product information (ePI) cross-industry taskforces.

Hilmar Hamann, Head of Information Management Division, EMA

Dr. Hilmar Hamann joined the European Medicines Agency in January 2020 as the Head of Information Management with a focus on implementing and promoting EMA's vision for a modern, efficient and data-driven agency of the future. Prior to joining EMA from 2011 to 2020, he served as the Director for Business Informatics at the U.S. Food and Drug Administration leading the transformation of medicines regulatory data, advancing data analytics, and modernizing the scientific computational and collaboration platforms that underpin operations. From 1996 to 2011, Dr. Hamann worked at a leading international consumer goods company in client-facing IT management roles bridging the communication gap between business and IT, where he led large-scale enterprise IT initiatives to transform commercial, manufacturing and supply chain operations across Pharmaceuticals, Health and Beauty Care business units. Dr. Hamann received his Ph.D. and Master's Degree in Chemistry from the University of Göttingen where he worked onexperimental and theoretical investigations in the field of molecular physics and chemical kinetics and the development of complex algorithms for simulating and modeling intra-molecular dynamics of small molecules in the stratosphere. He was awarded the FedHealthIT 100 Award three years in a row between 2018-2020 and received the FedHealthIT Innovation Award in 2018.

Kristiina Puusaari, Programme Coordinator/Project Manager Digital Change Workstream Digital Business Transformation Task Force, EMA

Kristiina joined the European Medicines Agency in January 2002 and has been focusing on implementation of electronic submissions at the agency since 2006. Kristiina is responsible for the implementation, coordination and maintenance of the eSubmission systems and processes at the agency and is a product owner for DADI project which will delivery replacements for the pdf format eAFs for the EU network.

Kristiina is a subject matter expert for eCTD v3.2.2, eCDT v4.0, the electronic Application Forms (eAFs), the eSubmission Gateway and Web Client, the Common Repository, the PSUR Repository and the business processes related to the eSubmissions. Kristiina works closely with the business and technical colleagues and the development teams.

Kristiina works closely with colleagues from the European Medicines Network (EMRN) and the pharmaceutical industry. Kristiina represents the EMA in eSubmissions related stakeholder groups and represents the EU region as the Regulatory Chair at the ICH M8.

Georg Neuwirther, Head of IT Austrian Medicines and Medical Devices Agency (AGES MEA), Chair of the eAF Maintenance Group, Co-Chair SPOR Taskforce since December 2021.

As Head of IT at AGES MEA, he is responsible for the agency's IT strategy and IT portfolio management, with a focus on solutions that enable innovation in business processes. This includes efficient data and process integration in EU initiatives. As a result, Mr Neuwirther introduced a new IT system called PHAROS, which replaced legacy systems. This flexible solution is the basis for ongoing and further national developments and integration into Europe-wide initiatives such as the implementation of CTIS, UPD, SPOR and others. Mr Neuwirther works closely with colleagues in the European Medicines Regulatory Network (EMRN - EMA and NCAs). He chairs the eAF MG and was a member of the EU Telematics Management Board before taking on the role of SPOR TF Co-Chair in December 2021. Mr Neuwirther holds a degree in Computer Science from the Vienna University of Technology (TU Wien) and has held various IT positions (operational and management) for 21 years. He has extensive experience in the execution of complex projects, software development and the transformation of IT organisations and business processes. He focuses on creating business value through agile methodologies with a clear strategic focus and dedicated execution of the project portfolio.

Karin Gröndahl, Business Development Manager, Swedish Medical Products Agency

Karin Gröndahl is a pharmacist with a degree from Uppsala University. She has been working at the MPA since 1988 in different positions; within the laboratory, as biotechnology/quality assessor, as Head of Registration and Information management and currently as Business Development Manager. She has a focus on regulatory and IT related business development.Karin has for a long time been deeply involved in the eSubmission area, both at the MPA and at EU level. She is currently member of many telematics related groups such as the eSubmission Expert Group, Human Harmonisation Group, Regulatory Optimisation Group, SPOR TF, and the Union Product Database Project Group.

Javier Monvoisin, Global Head 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 the head 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.

Session 6 - Prioritising regulatory reforms to increase access to medicines and to mitigate shortages

9 February 2022, 14.30 - 16.30

Adrian van den Hoven, Director General, Medicines for Europe

Adrian van den Hoven joined Medicines for Europe as a Director General in September 2013. His priorities at Medicines for Europe are to stimulate competition in off-patent medicine markets, to foster market access for generic, biosimilar and value added medicines, to support policy measures for sustainable pricing, to promote high regulatory standards while ensuring that the associated costs can be integrated into market dynamics and to develop a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value added medicines industries. Prior to joining Medicines for Europe, Adrian van den Hoven was Deputy-Director General of BUSINESSEUROPE where he was responsible for the International Relations department, covering trade negotiations and bilateral relations, and the Industry department, covering industrial, energy, environmental and research policy. He previously worked as an International Relations researcher and an adjunct professor in Italy (EUI), France (Nice) and Canada (Windsor). He obtained his doctorate in Political Science from the University of Nice, France in 2000.

Beata Stepniewska, Deputy Director General, 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.

Dolors Montserrat, Member of the European Parliament, EPP

She is a lawyer and currently serves as an MEP in the European Parliament. She is head of the Spanish EPP Delegation; Chair of the Committee on Petitions; member of the Committee on the Environment, Public Health and Food Safety; co-chair of the Health Working Group in the ENVI Committee; member of the European Parliament's Special Committee on Combating Cancer and European Parliament Representative in the Davos Alzheimer's Collaborative. Previously, between 2008 and 2019 she was a member of Congress for Barcelona. Throughout the X legislature, she was third Vice President of the Bureau of the Congress of Deputies. Former Minister of Health, Social Services and Equality from 2016 to 2018 and Spokesperson of the PP in the Congress of Deputies.

Olga Solomon, Head of B5 Unit, DG Sante

Olga Solomon studied Chemistry at the Aristotle University of Thessaloniki, Greece and holds an MSc in Food Science from the Gothenburg University, Sweden. Before joining the European Commission she worked for 5 years for a beverage producing company in Greece. She joined DG SANCO in 2000 and worked for 10 years in the field of Food Safety in particular dealing with legislation on Food Contact Materials, Food Additives and Enzymes. In 2010, she moved to the Directorate 'Health Systems and Products' where she worked in the field of substances of human origin before taking up a post in the pharmaceutical sector in 2011. She is currently the Head of the DG SANTE Unit responsible for Medicines: policy, authorisation and monitoring.

Emer Cooke, Executive Director, 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) for a term of 2 years. 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.

Christa Wirthumer Hoche, Head of the Austrian Medicines Agency (AGES), AT

DI Dr. Christa Wirthumer-Hoche studied biochemistry at the Technical University in Vienna and did her doctoral thesis at the Institute of Medical Physiology in 1983. First at the Austrian Institute for Drug Control (1983 - 1998), her area of responsibility was the quality assessment of medicinal products, and from 1998 at the Federal Ministry of Health and Women's Affairs, she was Head of the Marketing Authorisation Department for Medicinal Products. Since the founding of the new Austrian agency on 1 January 2006, she has been Head of the Institute for Market Authorisation and Lifecycle Management of Medicinal Products. Since October 2013, she has been Head of the Austrian Agency for Medicinal Products and Medical Devices at AGES (Austrian Agency for Health & Food Safety), and a leading member of BASG (Federal Office for Safety in Health Care).
Since 1994, she has been a member of several European committees and working groups, and is currently also elected Chair of the EMA (European Medicines Agency) Management Board. As a guest lecturer, she teaches the subject "Regulatory Affairs of Medicinal Products" at several European universities.

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. 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).

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.

Remco Munnik, Chair of the Telematics Group Medicines for Europe, Iperion

+20 years in experience in Life Science and Regulatory Affairs, 10+ years consultancy with focus on Regulatory Information Management (RIM) and electronic submissions.
- Strategy & Project manager
- Subject Matter Expert for Regulatory Information Management systems (RIM), eCTD, xEVMPD and ISO IDMP
- Member of EMA ISO IDMP Task Force Organizations and Products
- Chair Medicines for Europe Telematics group (eAF, eCTD, CESP, xEVMPD and ISO IDMP)