

2022 Annual Conference

Sitges (Barcelona)

29 JUNE – 1 JULY 2022 – #ACCESSFORALL

SPEAKERS AND CHAIRPERSONS



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, foster access to medicine, support policy measures for sustainable pricing, promote efficient regulatory standards and develop a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value added medicines industries. Adrian is the former President (and current Member of the Board) of the European Medicines Verification Organisation (EMVO) for the implementation of serialisation against falsified medicines. Prior to joining Medicines for Europe, Adrian van den Hoven was Deputy-Director General of BUSINESSEUROPE where he was responsible for the International Relations Industry departments. He previously worked as a researcher in Italy (EUI), France (Nice) and Canada (Windsor). He obtained his doctorate in Political Science from the University of Nice, France in 2000.



Stella Kyriakides, Commissioner, Health and Food Safety, European Commission

Ms Kyriakides, in her capacity as the European Commissioner for Health and Food Safety since December 2019, is leading the Commission's work on various portfolios including the Europe's Beating Cancer Plan, aiming to improve cancer prevention and care while also she is in charge of developing a new Pharmaceutical Strategy to ensure that Europe can meet its needs relating to affordable medicines. During the COVID-19 crisis, the Commissioner took on the responsibilities of coordinating the EU's health response and of supporting Member States to tackle the outbreak. Ms. Kyriakides has previously worked as a clinical psychologist for 28 consecutive years, in the Mental Health Services of the Ministry of Health of the Republic of Cyprus in the area of Child and Adolescent Psychiatry, from 1979-2006. Ms. Kyriakides was elected to the Cyprus Parliament in 2006 and was then re-elected in 2011 and 2016 for the Democratic Rally Party, for which she served duties as Vice-President. In 2012, Ms. Kyriakides was appointed Head of the Cyprus Delegation to the Parliamentary Assembly of the Council of Europe (PACE) and in 2017 she was elected as President of PACE, thus becoming the 30th President of the Assembly. Notably, she was also the founder of the First Breast Cancer advocacy organization in Cyprus, namely "Europa Donna – Cyprus" and served as the President from 2000-2015. She was also President of the European Breast Cancer Coalition Europa Donna.



Paul Csiszar, Director, DG Competition, European Commission

After graduating from ELTE School of Law of Budapest, Paul Csiszár studied international comparative law and earned a second Juris Doctorate at Loyola Law School in the United States. Following his admission to the California Bar in 1986 he practiced as a corporate, securities and M&A lawyer in the US and then from 1997 in Europe with the international law firm of Squire Sanders until 2003 when he joined the public sector. Currently Mr Csiszár serves as one of the Directors of the Directorate General for Competition of the European Commission.



Agnieszka Deeg-Tyburska, Head of Legal, General Counsel, Commercial Proxy, Polpharma

Agnieszka Deeg-Tyburska has been working as the Chief Legal Advisor of the Polpharma Group since 2015. Currently, he manages the legal, organizational, compliance, security and patents teams. She is also the Vice-President of the Legal Committee of Medicines for Europe. Since 2022 she holds the title of Certified CERP Mediator. Agnieszka has been associated with the pharmaceutical industry for many years, representing generic and innovative producers in regulatory and patent related matters as well as in large and sophisticated transactions.

She has extensive experience in M&A transactions with particular emphasis on acquisitions of public companies, investment transactions of venture capital funds.



Ingrid Sollerer, General Counsel & Global Head Legal, Sandoz

Dr. Ingrid Sollerer is Global Head Legal and General Counsel at Sandoz. She joined Sandoz GmbH, Austria in April 1998 and moved on to Novartis International AG in Basel, Switzerland where she held the position of a Senior Corporate Counsel, Mergers & Acquisitions and Competition Law from 2001 to 2007. Since 2008 she was heading the Legal Departments for Western Europe, Middle East/Africa, the global Business Units Oncology Injectables and Anti-Infectives and holding the position of the Global Head Legal Biopharmaceuticals and Deputy General Counsel at Sandoz. In 2016 she joined Novartis Oncology as Global Head Legal Transactions and Cell&Gene in East Hanover, USA before rejoining Sandoz in 2019 in her current role. Ingrid holds a degree of law from the University of Innsbruck, a Diploma of international law at the University of Seville/Spain and obtained a doctorate in law in 2001 at the University of Innsbruck.



Ana Marti, General Counsel & IP, Medichem

Ana Marti is General Counsel at Medichem, S.A., a Spanish headquartered company devoted to the development and manufacture of active pharmaceutical ingredients and generic medicines. Her role includes, in addition to legal, IP and regulatory affairs of the group of companies. She has more than 20 years' experience in the pharmaceutical industry, mainly acquired in the generic sector. She is qualified as a Spanish attorney at law and completed executive education at ESADE Business School. Before joining Medichem, she worked several years at a Spanish law firm advising life science clients on commercial transactions and regulatory and IP matters. Ana has also participated as co-author of a book on pharmaceutical marketing and is currently member of the Board of Medicines for Europe.



Tomos Shillingford, General Counsel, InsudPharma

Tom is General Counsel at Insud Pharma, a diversified biopharmaceutical business based in Madrid, Spain. Tom's previous positions were as Director IP Litigation at Insud Pharma and Allergan. Tom is a triple qualified lawyer (England and Wales, Australia, Spain), whom previously worked in private practice in London with Bird & Bird and in Melbourne with Herbert Smith Freehills. Tom has been working in the pharmaceutical industry for over 13 years and has a wealth of experience in patent litigation and pharmaceutical law across the globe. In his previous role, Tom managed many prominent patent actions, including Actavis v Sanofi (Irbesartan HCT), Actavis v Boehringer Ingleheim (Telmisartan HCT), Actavis v Warner Lambert (Pregabalin) and Actavis v Eli Lilly (Pemetrexed).



Bibianne Bon, SVP and General Counsel Europe, Teva

Bibianne Bon is SVP & General Counsel Europe at Teva. She currently leads Teva's European legal team responsible for the legal support to the commercial organizations, as well as the manufacturing and R&D sites in Europe. She joined Teva in 2010 from Allen & Overy LLP, where she specialized in corporate and commercial law. Initially, Bibianne focused on corporate and corporate governance matters; she has worked on many of Teva's acquisitions. Over the years, Bibianne gained broad pharmaceutical experience while supporting various European markets and acted as General Counsel Benelux before her current role. Bibianne has a Master degree in European, International and Dutch law from the University of Groningen, the Netherlands.



Elisabeth Stampa, CEO, Medichem and President Medicines for Europe

With more than twenty years in the industry, Elisabeth is currently CEO of Medichem SA and serves on its Board. Since 2016, together with the Executive team, she has transformed the company from a pure API player into a vertically integrated B2B company. She has driven both innovation and sustainability initiatives within Medichem SA. Prior to becoming CEO, Elisabeth was Executive Chair of the Corporate family business (Medichem SA and the former Combino Pharm SL), having started her career in Marketing at Laboratorios Esteve. She holds a BSc in Pharmacy (UB, Spain) and an MBA (ESADE Business School, Barcelona, Spain). She also serves on the Board of Trustees at the IQS in Barcelona. Elisabeth has been an active member of international associations throughout her professional career and advocates for legislative changes that improve patient accessibility and strengthen the European industry at a global level. She represented EU API manufacturers on behalf of EFCG in the GDUFA II negotiations with FDA.



Margaritis Schinas, Vice-President, European Commission

Margaritis Schinas took office as Vice-President for Promoting our European Way of Life in the Von der Leyen Commission in December 2019. In this capacity, he oversees the EU's policies for migration, security union, social rights, skills, education, culture, youth, health and dialogue with churches, religious associations and non-confessional organisations. Mr. Schinas started his career in the European Commission in 1990. He also served as a Member of the European Parliament, from 2007 until 2009. Upon the completion of his parliamentary term of office, he returned to the European Commission and held various senior positions. In 2010, President Barroso appointed Mr Schinas as Deputy Head of the Bureau of European Policy Advisers. Later he served as Resident Director and Head of the Athens Office of the European Commission's Directorate-General for Economic and Financial Affairs (DG ECFIN). In 2014, President Juncker appointed Mr. Schinas as the European Commission's Chief Spokesperson. Margaritis Schinas holds an MSc on Public Administration and Public Policy from the London School of Economics, a Diploma of Advanced European Studies on European Administrative Studies from the College of Europe in Bruges and a Degree in Law from the Aristotelean University of Thessaloniki. You can follow him on Twitter: Margaritis Schinas (@MargSchinas).



Suzette Kox, M.Sc., Pharm., Secretary General, IGBA

Suzette Kox is the first Secretary General of the International Generic and Biosimilar Medicines Association. She was nominated in January 2019, after 17 years in various functions at Medicines for Europe. Adopting a patient centric approach, IGBA works to improve patients' access to quality-assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders. Before joining the generic medicines industry in 1992, Suzette followed a hospital and retail pharmacy career. Along with a degree in pharmacy (Paris), she holds a postgraduate diploma in anatomy-pathology (Cochin Port Royal, Paris).



Per Troein, Vice President, Strategic Partners, IQVIA

Per Troein has been with IQVIA for more than 20 years and is responsible for the relationship with suppliers and associations. The focus on availability and affordability is on the top of the agenda both in EU and Nationally. The present system does not succeed to generate availability of all new medicine around the region. We also experience shortages of a broad range of products on an interim basis. The cost for pharmaceuticals is going up in absolute terms but is constant relative to healthcare cost. One of IQVIA's priorities is to have the best understanding of those dynamics to secure the most appropriate data, to be the best partner with the different data partners, and to be able to support the industry, associations and also when appropriate governments. He is a well know speaker in the field of distribution trends and pricing and is very active in consulting projects in the area. Prior to joining IMS, Per worked 13 years for Pharmacia in US and Europe. He holds an MSc in engineering from Lund's Institute of Technology and an MBA from INSEAD.



Victoria Romero Pazos, Tripleaxel

She works as freelance project manager, community manager in the field of health and legal advisor specialised in disability. Currently she manages the secretariat of OPENREUMA, the Spanish Association of Health Professionals in Rheumatology, and she coordinates the logistics for an international project in Fibromialgia. She has now created TripleAxel.net which combines all her professional work in different fields. She has been acting as international representative and patient advocate for more than a decade. She is Past Chair of the board of LIRE and current EULAR-PARE liaison officer, she is also Past Chair of the Agora Platform. She continues to work with these patient organisations and also for several public institutions and schools doing seminars and workshops explaining and promoting universal accessibility and inclusion, trying to raise awareness about disabilities and invisible illnesses.



Rebecca Guntern Flückiger, Head Region Europe, Sandoz International

The basis for Rebecca Guntern Flückiger's professional success is her passion for what she achieves with her work. At the age of 36, she was taking on the management of Sandoz Switzerland in 2008, and from 2011 she managed the business in Spain. In 2013 she then moved to the Sandoz headquarters and shortly thereafter assumed responsibility for various country clusters. Since January 2020, as Head Region Europe, she has been responsible for over 40 countries in Western and Eastern Europe with a business volume of over five billion US dollars. As Vice-President of Medicines for Europe, she is committed to drive sustainable healthcare in Europe and believes that access to healthcare should be a right, not a privilege. She is also a member of the Board of Directors of BKW Energie AG.



Dirk Van den Steen, Deputy Head of Unit at DG SANTE

Dirk Van den Steen is an economist working at the European Commission's Directorate General For Health and Food Safety (DG SANTE) as Deputy Head of the unit covering the performance of national health systems. Prior to joining the Commission in 2009, Dirk worked at the actuarial department of the Belgian public payer organisation RIZIV/INAMI dealing with the database architecture of hospital billing/clinical information, the Belgian Healthcare Knowledge Centre (KCE) as a health economist involved with health technology assessment (HTA) and with IMS Health (now called IQVIA) as a consultant in pharmaco-economic modelling for the pharmaceutical industry. At the European Commission in the past Dirk has been involved in the development of the Cross-border Healthcare Directive, notably working on the mutual recognition of cross-border prescriptions as well as the assessment of national health systems. In the area of medical products at the European Commission Dirk also worked at the European Commission DG for Competition on antitrust enforcement in the domain of pharmaceuticals, devices and health services as well as on the Pharmaceutical Strategy for Europe, notably with regard to access to affordable medicines.



Maja Sercic, Associate Director Policy & Market Access, Medicines for Europe

Maja Sercic is an Associate Director Policy & Market Access for Medicines for Europe, a trade association representing the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value-added industries. In her role, she focuses on issues such as equitable access to affordable treatments across Europe, achieved by sustainable pharmaceutical market for off-patent medicines and innovation throughout the medicines life cycle, in the form of Value Added Medicines. She holds the Master of Sciences of Pharmacy degree obtained from Faculty of pharmacy, University of Ljubljana. Before joining Medicines for Europe, she worked in the pharmaceutical industry. Medicines for Europe is a leading partner for better healthcare aims to increase the health and wellbeing of all Europeans through better access to high-quality medicines.



Cristina Montané, Citizen Participation Director, Foro Español de Pacientes (FEP)

Cristina Montané, a patient linked to patient associations in which she has worked as a volunteer for more than twenty years. She completed the Postgraduate Course in Patient Advocacy at the UIC. She is member of the Catalan Patient Advisory Council, patient representative at the Catalan Health System Committee for Medical Products for Human Use, Territorial Coordinator and Patient Advocate of ACAF - Catalan Association of People Affected by Fibromyalgia and other Chronic Fatigue Syndrome, Secretary of the FM-SFC-SQM Family Platform, and consultant of Foro Español de Pacientes (FEP).



James Burt, Chief Executive Officer (CEO), Pharmanovia

James joined Pharmanovia in October 2021 as CEO. Before joining he was the Executive Vice President EMENA at Accord Healthcare and oversaw branded and generic pharmaceutical activities across 65 markets. Prior to this, he served as Vice President Hospital Business at Actavis, where he was responsible for the strategic direction of secondary-care activities worldwide. He holds a PhD in Chemical Engineering from the University of Birmingham, with a particular focus on biopharmaceutical manufacturing.



César Hernández García, Head of Department, Department of Medicines for Human Use, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Dr. César Hernández MD, PhD. joined the Spanish Agency for Medicines and Medical Devices as a Head of the Human Medicines Department in 2009. Prior to joining the Agency, he was the deputy Medical Director of the Hospital Clínico San Carlos in Madrid for three years. He previously worked as rheumatologist at the same Hospital for 16 years also developing functions as associate professor of Medicine and principal and associate investigator in several research projects financed by public and/or private funds in areas such as basic research, clinical research and health care services. He graduated from medicine and surgery, specialist in Rheumatology in 1987 at the Complutense University of Madrid and received his PhD in 1996 at the same university.



Florian Schmidt, Deputy Head of Unit Medicines: Policy, Authorisation and Monitoring, DG Sante

Florian Schmidt is the deputy head of unit of the Commission's pharmaceutical unit B.5 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.



Frances (Fran) M. Zipp, President & CEO, Lachman Consultant Services, Inc.

Fran Zipp is President & CEO of Lachman Consultant Services, Inc. As an expert in compliance enhancement, she develops program solutions to meet GXP compliance requirements and delivers strategic guidance and direction toward implementation of effective solutions to client needs. Ms. Zipp has extensive experience in the pharmaceutical, biologic and biotechnology industries from R&D through post-market approval. She assists and counsels Senior-level management in areas of Corporate Governance, Corporate Integrity Agreement Compliance, Consent Decree Negotiations and Resolutions, Application Integrity Policy resolution, and Due Diligence evaluations (facilities; products; technologies).



Adele Paterson, CEO, International Health Partners

As CEO of the global health charity International Health Partners (IHP), Adele leads its work to increase access to essential healthcare products for those in vulnerable and disaster hit communities. Last year, IHP delivered 14.5 million treatments supporting 6.8m people in 31 countries. Under Adele's leadership, IHP has initiated rigorous ways to measure the long-term impacts of its work; quadrupled the number of treatments shipped; established a secure, diverse and growing income stream; and has developed a software business bringing supply chain efficiencies, best practice and impact measurement to product donations. Adele joined IHP after working as head of policy for a financial trade association and prior to this, headed CSR, fundraising and communications for a national regeneration charity. An economics and politics graduate, she started her career as a political researcher, running the parliamentary office of a UK government minister. Adele is Treasurer of Integral Alliance, a union of 22 global disaster response agencies, and sits on the Board of the Anglican Communion Fund supporting the international ministry of the Archbishop of Canterbury in 165 countries.



Tom Roane, Vice President, Corporate Engagement & Strategy, Direct Relief

Tom Roane serves as Vice President of Corporate Engagement & Strategy for the global medical relief non-profit Direct Relief, an organization founded over 70 years ago which will provide over \$2 Billion this year in donated medical products to vetted and qualified public hospitals and clinics in over 100 countries around the world, including within Europe and the United States. Roane has over two decade's experience in establishing and managing Rx access and medical support programs in all regions of the world to help underserved patients access their required treatments, as well as 8 years' experience in business development and marketing management with big pharma and start up biotechnology companies. His expertise in the design and implementation of creative and impactful ESG programs have opened opportunities for drug access for underserved patients with cancer, diabetes, rare disease, and non-communicable diseases. All of the world's largest pharmaceutical corporations have trusted relationships with Direct Relief, which has become the largest global non-profit provider of humanitarian medical relief for the world's at-risk and underserved, including in Ukraine where Direct Relief is working hand in hand with the country's health ministry and other strategic partners in providing into Ukraine many hundreds of tons of requested and required vital medical products.



Victor Mendonça, Head of Corporate Affairs - Europe - Viatriis

Victor Lino Mendonça is the Head of Corporate Affairs for Viatriis in Europe and Board member of Medicines for Europe. Formerly, he was leading the Health Economics department at Medicines for Europe. He was also Advisor to the Executive Board of INFARMED for almost 8 years and prior to this, was the Advisor to the Health Secretary of State to the Ministry of Health in Portugal. He has more than 20 years of experience in pharmaceuticals sector having also worked in FMCG sector. Victor graduated in Business Administration by Universidade Católica Portuguesa in Portugal.



Clement François, MSc, PhD, DSc, Executive Vice President, Pricing and Market Access, Creativ Ceutical

Clement worked for the Public Health department in Marseilles University Hospital, before embarking on a career in the pharmaceutical industry. He worked at Lundbeck for 19 years as Executive Director for Global HEOR and Epidemiology and Vice president HEOR for the US affiliate. Since 2017 Clement is executive vice president of HEOR and Market Access at Creativ Ceutical. In parallel to a private career, Clement works as associate researcher in the Public Health Department – Research Unit EA 3279 of the Aix Marseille University. Clement demonstrates competencies in HEOR, Healthcare System Pharmaco-epidemiology, Pricing, Market Access, Data Analytics and Real World Evidence, lead multidisciplinary and multinational teams and has supervised over 60 HTAs submissions. He has a MSc in Mathematics from the University of Toulouse, a Diploma from the University of York in Health Economics, a PhD in health sciences from Marseille University, a Doctorate of Science in Economics & Outcomes Research (Sc.D.) from the University of Lyon and has authored more than 200 articles, communication or posters in the field of health economics and epidemiology.



Thyra de Jongh, Principal Consultant, Technopolis Group

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.



Cláudia Furtado, Head of Information and Strategic Planning Office, Infarmed

Cláudia Furtado is the head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) as well of the Information and Strategic Planning Division (DIPE) at INFARMED, the Portuguese National Authority of Medicines and Health Products. As head of DATS, she is responsible for HTA evaluation, pricing and reimbursement of medicines, medical devices and health products, and for managed entry agreements. As head of the DIPE, she oversees monitoring of health consumption and expenditure and the definition and evaluation of policy measures. In addition to her role at INFARMED, she is an assistant professor at the Portuguese National School of Public Health (Universidade NOVA de Lisboa).



Gergely Németh, Project Manager, National Institute of Health Insurance Fund Management (NEAK)

Gergely Németh graduated as a pharmacist in 2004 in Budapest. He has been working at the department in charge of reimbursement of pharmaceuticals of the Hungarian authority for health insurance. He has been involved in the planning and implementation of the Hungarian generic pricing policy since 2007 and participated in the development of softwares supporting pricing and reimbursement of pharmaceuticals. He has been the project manager of the EURIPID project since its establishment in 2010. The EURIPID project is a non-profit initiative of the national competent authorities of Europe for the mutual sharing of pharmaceutical price information.



Valérie Fontaine, Executive Vice President, Fresenius Kabi & member of the Medicines for Europe executive committee

Valérie is an Executive member of Fresenius Kabi and worked in the pharmaceutical industry for almost 3 decades. She has a scientific background and sales & marketing experience. In her role as Executive Vice President of Commercial Strategy and Operations she ensures that the countries receive the medicines and medical devices needed. She has a thorough knowledge on EU member states national specificities and on how these specificities are accommodated in the registration and pricing policy of medicines, to allow for more access to medicines for patients in the EU.



Aidan Fry, Director External Communications, STADA Group

Aidan Fry is Director of External Communications at STADA Arzneimittel. In this role, which he has held since February 2020, Aidan oversees communications with key stakeholders across the group's 120-plus markets and activities encompassing generics, specialty medicines and consumer healthcare products. He also coordinates STADA's participation in key industry associations, including Medicines for Europe and the International Generic and Biosimilar medicines Association. Aidan has more than 20 years of experience in the off-patent medicines sector, including as a co-founder and editor of Generics Bulletin, the industry-leading business-to-business newsletter.



Philippe Drechsle, Vice President EU Portfolio, Teva & member of the Medicines for Europe executive committee

Economist and certified accountant by education, Philippe has been working in the generics industry for over 20 years in various functions spanning from controlling/finance, demand management, product administration, area management, business development, product portfolio optimization, to special projects such as FMD project lead. He is currently responsible for EU Portfolio, in charge of generics product selection, launches and life-cycle management.



Monica Dias, Head of the Supply and Availability of Medicines and Devices, European Medicines Agency (EMA)

Since 1 October 2021, Dr. Dias is Head of supply and availability of medicines and devices, a.i. at EMA. She is responsible for the implementation of the extended mandate of EMA in the area of shortages of medicines and devices and she is now Co-Chair of the HMA/EMA HMA/EMA TF AAM. Dr. Monica Dias studied pharmacy in Lisbon, Portugal and obtained her PhD from the University of Cardiff, UK. Dr. Dias joined the European Medicines Agency in 2004. She worked in the Quality Office for 10 years. In March 2013 she joined the Office of the Deputy Executive Director at EMA where she was Principal Policy and Crisis Coordinating Officer. She was involved in the development of policies, best practice guidance for the anonymisation of clinical reports, and coordinated the Brexit operational preparedness activities at EMA, including the impact of Brexit on the availability of Centrally Authorised products. Dr Dias was also coordinating at EMA the activities of the HMA/EMA Task Force on the availability of authorised medicines (HMA/EMA TF AAM) and she was a Co-Chair of Thematic Working Group 1 of the Task Force. She chairs a Network for sharing information between Member States, EMA and the EC on critical medicine shortages, an initiative undertaken in the context of the work programme of the EMA/HMA Task Force. During the COVID-19 pandemic Dr. Dias coordinated activities in relation to shortages due the pandemic both at EMA and with the NCAs. She was involved in the setting up the mechanisms to monitor shortages of medicines (EU Executive Steering Group on shortages) and was leading a Working Group which developed a common framework for forecasting demand data in the EU/EEA.



Nicolás González Casares, Member of the European Parliament

Born in A Coruña (Galicia-Spain) in 1972, he studied nursing at the University of Santiago de Compostela, working in 061 -Emergency service- and as a specialist teacher in life support, where he is the author of the Manual of advanced life support in pre-hospital emergencies (2007) among other health publications. In parallel, Gonzalez Casares has developed his political career at the local level, becoming first deputy mayor and councillor for Urbanism, Social Services, Health and Sport during the previous legislature in Lalín, a village in the heart of Galicia. After the elections to the European Parliament in May 2019, he became an MEP for the PSOE. In the European Parliament, he is a member of the Committee on Industry, Research and Energy - ITRE, where he is the spokesperson for the Spanish Socialist Delegation for Energy -, the Committee on Environment, Public Health and Food Safety Committee (ENVI) and the Committee on Fisheries (PECH).

González Casares has been the Socialist rapporteur in ITRE for the Regulation (EU) 2021/1119 of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law'). Within the Fit for 55 package, he's the Socialist rapporteur for the proposal to revise the Renewable Energy Directive and ENVI's rapporteur for the Proposal for a regulation on ensuring a level playing field for sustainable air transport (ReFuelEU Aviation). González Casares has also been the Parliament's rapporteur for Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. He's also been a member of the Special Committee on Beating Cancer and the Socialist shadow rapporteur for its report.



Ancel·la Santos is Senior Health Policy Officer, The European Consumer Organisation (BEUC)

Ancel·la Santos is Senior Health Policy Officer at the European Consumer Organisation (BEUC), which brings together 46 consumer organisations from 32 countries. She follows closely EU pharmaceutical policy and defends consumer interests in this area. Before joining BEUC in May 2019, Ancel·la served as Senior Policy Advisor for Health Action International. In total, she has nine years' experience representing the positions of non-profit umbrella organisations before the EU institutions, and at the European Medicines Agency's Patients' and Consumers' Working Party. From 2011-2013 Ancel·la worked at the Siemens AG Representation Office in Brussels, in the healthcare sector. She holds a Bachelor's degree in Political Sciences and Public Administration, a Master of Science in International and European Politics, and a Master in Journalism.



Domenico Di Giorgio, Ph.D, Head of Inspection and Certification Department and of the Pharmaceutical Crime Counteracting Office, Italian Medicines Agency (AIFA)

Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention. As an expert in pharma crime counteracting, he published many books (for CoE/EDQM, WHO and the Italian State Library), chaired the EDQM/Council of Europe Committees CMED (Counterfeit medicines) and

CDPPH (Steering Committee Pharmaceuticals), developed and coordinated EC funded projects such as FAKESHARE I and II, and is currently European vice Chair of the WHO Member State Mechanism and coordinator of the EC MEDI-THEFT project. He led the Volcano Operation, an international operation against a huge infiltration of falsified medicines in the European network, and coordinated the publication of the related White Paper for the EC. He is dealing with medicines shortages since 2015, as coordinator of the “National Ad Hoc Forum on Short Supply of Medicines”; in 2021 he coordinated the development of the project CHESSMEN, a proposal for a 2022-2025 European Joint Action against Shortages (currently in the approval procedure), involving 24 Countries.



Jordi Valls – Vice President, AFAQUIM

Degree in Chemistry for the University of Barcelona

10 years of experience in the pharma industry having several responsibilities in production of sustained release Drug Products and other solid dosage forms.

In 1998 I moved to the APIs business joining Moehs Group as corporate Quality Assurance Manager.

Since 2006, Chief Technical Officer of Moehs Group being corporate responsible for R&D, Quality Assurance, Regulatory Affairs and Intellectual Property. Member of the Management Board of Moehs Group.

Active member of the Quality and Regulatory Affairs Groups of AFAQUIM and APIC/CEFIC. Vice President of AFAQUIM since December 2021.



Mar Fábregas, President, AESEG

Mar Fábregas has been Managing Director of STADA Spain since 2013. With more than 25 years of experience in the pharmaceutical industry, she previously assumed the responsibilities of Chief Operating Officer (2010) and Business Development Director (2005) at STADA Spain, and Global Strategic Purchase Manager at STADA Arzneimittel AG. Previously, she joined Sandoz – Novartis Group – (1999) and Chiesi (1997), assuming responsibilities of Launch and Portfolio Management. In February 2022, she was appointed president of the Spanish Association of Generic Medicines (AESEG). She was previously appointed vice president of AESEG (2020). She is currently part of the Board of Directors of the Association for Self-Care of Health (ANEFP). Mar Fábregas has a degree in Pharmacy from the University of Barcelona, a Postgraduate Degree in Business Management from the Pompeu Fabra University and a General Management Program from IESE University of Navarra.



Patricia Lacruz – Director General for Pharmaceuticals, Ministry of Health, Spain



Michele Uda, Director General, Egualia & member of the Medicines for Europe executive committee

Italian association for accessible medicines, official representative body of the generic, biosimilar and value added medicines in Italy - MEMBER of the Executive Committee of Medicines for Europe - CHAIRMAN of the NAC (National Association Committee of Medicines for Europe). Graduated in Political Science from the International University LUISS Guido Carli in Rome, with a specialization in International Economics, after an initial experience in one of the largest Italian trade unions, he has successfully completed a full time MBA in International Business and Economics at "Mib School of Management" of Trieste. He then continued his career in the retail consumer sector at Ferrero Italy as Assistant Brand Manager for the Italian multinational company's core business and, later, at Colgate Palmolive Italy as a market and industry sales analyst in the Household Care division. He stepped into the healthcare sector joining Johnson & Johnson Medical where he was responsible for direct management of sales and marketing for the breast care line in Italy's central and southern regions. From March 2007 he joined EGUALIA (formerly known as Assogenerici, the Italian Generic and Biosimilar Medicines Association), as "Pharmaceutical Economics & Policy Affairs Manager", assuming direct responsibility of the Centre for Economics and Policy Analysis of the association. From April 2012 he has been appointed Director General of EGUALIA, keeping also the responsibility for international relations. Since 2014 is also managing IGB – Italian Biosimilars Group, representing the biosimilar medicines industry within EGUALIA and more recently the VAM – Value Added Medicine Group of EGUALIA. Member of the Executive Committee of Medicines for Europe (European Generic & Biosimilars Medicines Industry Association); appointed Chairman of the GMAC (Generic Market Access Committee of Medicines for Europe) in 2011, he is now Chairman of the NAC (National Association Committee of Medicines for Europe).



Pierre Delsaux, Director General, Health Emergency Preparedness and Response Authority (HERA), European Commission

Pierre Delsaux is Director-General to the European Health Emergency Preparedness and Response Authority (DG HERA). After studying Law at the University of Liège, he obtained his Master of Law at the Northwestern University, Chicago. He was Legal Secretary at the European Court of Justice. He worked in the private sector before joining the European Commission in 1991. He started his career within the European Commission in the Directorate General for Competition. In 2007, he was appointed Director responsible for regulating the financial services. In 2011, he was appointed Deputy Director General with responsibilities for the Single Market in the EU. From November 2015, he was in charge of Space Policy and Defence. On 01/01/2020 he was appointed Deputy Director General at the European Commission Directorate General for Defence Industry and Space (DG DEFIS). On 1st December 2021, he joined the Directorate General for Health (DG SANTE).



Dolores Montserrat, Member of the European Parliament

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.



Giacomo Mattinò, Head of Unit for Agro-Food, Retail and Health ecosystems – EC DG GROW

Giacomo Mattinò is a permanent official of the European Commission since December 1993. He has held several positions within the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, with more than 10 years in management positions, now Head of the Unit with policy responsibility for competitiveness and towards a well-functioning Single Market for the Agro-food, Retail and Health industrial ecosystems, leading directly a team of 18 staff members. The Unit is responsible for supporting these industrial ecosystems in the EU Single Market and globally by promoting effective industrial value chains ensuring fair trade practices and access to markets, and a fair and balanced regulatory framework. Strong focus is on targeted actions along sustainable, green and digital pathways. It also coordinates the industrial production dimension of health policies for DG GROW, including input to the Health Emergency Preparedness and Response Authority (HERA), the Structured dialogue on the security of medicines supply as well as in the COVID-19 EC Vaccines Task Force. Before the current management responsibilities he held management position as the Head of Unit for SMEs internationalization, Human Resources in the European Commission-Directorate General for Industry & Enterprises and had a strong career path in the Commission with focus on Internal Market and its International Trade dimension (mechanical and automotive industries, mutual recognition and market surveillance), having also served in the EU Delegation for the South Pacific in Fiji. Giacomo Mattinò is a graduated in Political Sciences - international economics at LUISS in Rome and has followed post-graduate courses in business management and international project management at IFAP – Rome, at the South Pacific University and at the Ashridge Management School. He is the author of several publications, in particular on trade and mutual recognition issues. He is a Lieutenant – Cavalry of the Reserve in the Italian Army with tank platoon leader and paratrooper qualifications. Giacomo, an Italian national, works fluently in English and French and has a satisfactory knowledge of Spanish and Portuguese.



Galo Gutiérrez Monzoní, General Director of Industry and SMEs

Training

Industrial Engineer, from the Higher Technical School of Industrial Engineers of Madrid. Polytechnic University, promotion of 1981.

Master in Business Management and Administration, Executive MBA, from the Instituto de Empresa, 1991.

Professional summary

Currently, General Director of Industry and Small and Medium Enterprises, since June 29, 2018.

Various positions in the General State Administration related to Industrial Policy and Business R&D, (2002-2018)

Previously in other positions in the public administration and private company.



Paul Tredwell, Executive Vice President, Accord Healthcare & member of the Medicines for Europe executive committee

Paul has over 25 years' experience in the pharmaceutical industry, predominantly on the speciality and biosimilar side of the business. On biosimilars Paul was the first to fully commercialise 3 biosimilars in a regulated market, collaboratively setting up the Biosimilar division of BGMA and acting as Vice Chair. Paul joined Accord in 2018, where he led the strategy of Accord's Speciality Brands division, playing a significant role in helping Accord to be one of the biggest suppliers of oncology medicines in Europe. Paul's pharma experience includes UK, Europe and Global management roles in commercial, business development and general management positions. Since July 2021, Paul has led Accord's operations in the EMENA territory, with responsibility for implementing and delivering the company's mission to increase access to high quality medicines within the region with an exceptional pipeline of generic, biosimilar and novel medicines and is responsible for a turnover of \$1bn with over 2000 employees.



Christian Pawlu, Head of Corporate Development, Fresenius Kabi

Dr. Christian Pawlu has been Head of Corporate Development at Fresenius Kabi AG since May 2021. In this role he is responsible, among other topics, for the company's global strategy, for transformational initiatives and for M&A. Prior to this role, he spent four years on the Executive Committee of Sandoz, responsible for Strategy, Portfolio, BD and the company's B2B business. Before that he was a partner at McKinsey and a leader in McKinsey's global healthcare practice with a specific focus on generic medicines. He is a licensed physician, was a researcher in neuroscience and has completed an executive program at the Harvard Business School. Christian Pawlu is a German national and has lived and worked in Austria, the UK and the US. Sustainable and affordable supply of medicines is one of Christian Pawlu's areas of expertise and passion. He has led company initiatives and external negotiations with governments on maintaining and strengthening the European manufacturing base for critical medications. As a speaker and panelist, Christian Pawlu aims to increase public awareness for the topic of medicines supply, which he sees as a major geostrategic challenge in our time.



Heikki Bothas, Executive Director, Finnish Generic Pharmaceutical Association

Heikki Bothas has been the Executive Director of the Finnish Generic Pharmaceutical Association for the last 14 years. He holds a Master's degree in Social Sciences (Social Policy) from the University of Helsinki. He has been described as an energetic one-man band by a rival lobbyist.



Joris Van Assche, Managing Director, Medaxes & member of the Medicines for Europe executive committee, Medaxes (Belgium)

Joris Van Assche (° Brussels, 1962) holds a Master of Laws (KU Leuven, 1986), together with degrees specialising in Economic Law (Université Catholique de Louvain, 1988) and Tax Law (Fiscale Hogeschool, Brussels, 1988). Joris started his career in 1988 as a Legal Advisor of Securex, a Belgian human resources group. From 1990 to 1994, he took the lead of the French subsidiary of Securex. In 1994 he was appointed Securex' Director Public Affairs. In 1995 he moved to pharma.be, the Belgian umbrella organisation of the originator pharmaceutical companies. After having served, between 1995 and 2002, as Deputy to the Managing Director, he was appointed Secretary General of pharma.be in 2002. Strongly motivated by the societal added value off patent medicines, Joris became in 2005 the Managing Director of Medaxes. In Medicines for Europe, Joris is currently Vice Chair of the National Associations Committee and is a member of the Executive Committee. In Belgium, Joris is Board member of several organisations active in the pharmaceutical sphere.



Isabel del Rio, Deputy Director, BioSim, Spain

Deputy director of the Spanish Biosimilar Medicines Association, BIOSIM (2020-present); previously project manager in BIOSIM (2016-2020). Researcher in molecular microbiology and bacterial genetics at Centre for Plant Biotechnology and Genomics (2007-2014).

Coauthor of Clinical governance, incentives and biosimilars (ISBN.: 9788490523001) and two papers on Spanish biosimilar landscape (<https://doi.org/10.3390/ph14030283> and <https://doi.org/10.3390/ph14040348>)

Education: PhD in Agricultural Engineering (2014) and Master in Agroforestry Biotechnology from the Polytechnic University of Madrid (2010), MBA from the University of Alcalá de Henares (2017) and Master in Health and Market Access-Pharmaco-Economics from the University Carlos III of Madrid (2020), Executive program in Leadership in Pharma-Biotech Industry from the Talento-Ephos School (2022)



Yannis Natsis, Director, European Social Insurance Platform (ESIP)

Yannis Natsis is the Director of the European Social Insurance Platform (ESIP), the umbrella organisation bringing together 45 national statutory social security institutions from 18 countries. ESIP is the voice of social protection and security in Europe or as Yannis puts it one of Europe's truest treasures. He has more than 10 years of experience in EU advocacy and policymaking. Prior to joining ESIP in February 2022, he led the advocacy for better and affordable medicines at the European Public Health Alliance (EPHA). In May 2019, he was appointed by EU Member States to the Management Board of the European Medicines Agency (EMA), a position he held until December 2021. Additionally, Yannis has been a Board member of the European Health Forum Gastein (EHFG), the leading EU health policy platform since 2018. Yannis previously worked for the TransAtlantic Consumer Dialogue (TACD) focusing on health and pharmaceutical policies. From 2006-2010, he was an investigative reporter for Greece's award-winning TV news programme "Fakeli" and a contributor to one of Greece's most respected dailies "Kathimerini". He has a Master's degree in International Conflict Analysis from the University of Kent, UK and a Bachelor's degree in European Studies from Pantion University of Social and Political Sciences, Athens, Greece. A Greek national, he is fluent in Greek, English and French.