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Tomislav Sokol

Member of the Committee on the Environment, Public Health and Food Safety, European parliament, (EPP – HR)

Tomislav Sokol was born in Zagreb in 1982. He obtained his first degree in law at the Faculty of Law, University of Zagreb, in 2006, magna cum laude. He then obtained a Masters of Law (LL.M.) specialising in European Union Law at the Katholieke Universiteit Leuven (KUL), Belgium, in 2009, magna cum laude. He defended his PhD at KUL, dealing with free movement of cross-border health care services in the EU and its impact on national health insurance systems in 2014. During his studies, in 2004, Tomislav Sokol became a Member of the Croatian Democratic Union (HDZ). He climbed the party ranks during the next decade, always emphasising on Christian Democratic values as the cornerstone of its identity. He was an Assistant Minister in the Ministry of Science and Education, after which he became a Member of the Croatian Parliament. He was a Member of the Croatian Parliament until July 2019, when he became a Member of the European Parliament. He is a Member of the Committee on the Internal Market and Consumer Protection and a Substitute Member of the Committee on Regional Development. So far, he has published around 20 papers and 1 book on issues concerning EU law, including several articles in European journals, such as the European Law Review and the European Law Journal. He has presented papers at many international conferences, worked on different research projects and is currently taking part in a Jean Monnet project related to EU health law and policy. Previously, he worked in a legal practice and is currently a Senior Lecturer at the Zagreb School of Economics and Management where he has taught Introduction to European Union and Principles of Law courses since the academic year 2010/2011. He is also an assistant professor at the Catholic University of Croatia where he has taught since the academic year 2016/2017. His areas of professional interest include the law of the European common market, EU health law, competition law, International and European social law and International and European trade law. MEP since 2019.

Cristian-Silviu Buşoi

Chair of the Committee on Industry, Research and Energy (ITRE) of the European Parliament

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Arun Narayan

Chair of the Value Added Medicines Sector Group, Medicines for Europe

Arun has a successful and diverse track record in fast growing, multinational pharmaceuticals companies, covering international expansion, portfolio strategy, M&A/licensing and operations; plus an entrepreneurial stint.

Kate O'Regan

Communications & Stakeholder Relations Senior Manager, Medicines for Europe

Kate is the Communications and Stakeholder Relations Senior Manager at Medicines for Europe, the trade association representing the generic, biosimilar and value-added medicines industry. Kate joined Medicines for Europe in 2017 after a number of years at the Association of European Cancer Leagues. Having worked more than ten years in the healthcare sector from within the European Parliament, industry, civil society NGO and trade association, Kate is a firm believer in the importance of integrating the patient perspective in healthcare dialogue both at the EU and nationally.

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Gilles Vassal, Prof, MD, PhD

Paediatric Oncologist at Gustave Roussy Cancer Center, France and Board Member of the European Society for Paediatric Oncology (SIOPE)

Trained as a Paediatric Oncologist, Gilles Vassal is Professor of Oncology at University Paris Saclay and received his PhD in Pharmacology. Former head of Clinical Research, he is currently heading the Paediatric Oncology Research program at Gustave Roussy Comprehensive Cancer Center in France. For the last 25 years, Gilles Vassal dedicated his research, clinical and training activities to the development of new drugs for children and adolescents with cancer and to regulatory science. Gilles Vassal is currently chair the EU academic consortium for Innovative Therapies for Children with Cancer (ITCC), a network that conducts a comprehensive new drug development program from the biology and preclinical evaluation to the early drug trials in 16 EU member states and Israel. He is Past-President (2013-2015) and currently Board Member of the European Society of Paediatric Oncology (SIOP Europe), in charge of the EU Paediatric OncoPolicy agenda. He is co-founder and Chair of ACCELERATE (www.accelerate-platform.org) – a multi-stakeholder international initiative to accelerate innovation for children and adolescents with cancer. Created in 2015, ACCELERATE is a partnership initiative between academia, industry, regulatory agencies (EMA , FDA and other regulatory networks) and patient advocate groups committed to improve and speed up the development of innovative therapy. He is co-leading the IMI2 ITCC-P4 project aiming at creating a sustainable platform for preclinical testing in paediatric oncology. He is co-leading the IMI2 Conect4children workpackage 4 on strategic advice and multistakeholder meetings. He has authored more than 250 publication and is member of several Scientific Councils.

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Orla Galvin

Executive Director, European Federation of Neurological Associations

Dr. Orla Galvin came to patient advocacy with a PhD in Medicine and background in drug discovery and design in both academic and industry environments. Transitioning to advocacy work at the umbrella patient organisation Retina International, Orla led high impact, multi-stakeholder socio-economic studies, patient preference studies, and accessibility studies across the globe assessing both rare and common conditions. Orla is an internationally invited speaker to both research and clinical learned societies (for example EURORDIS, EU Retina, ERN-EYE), patient organisations, and industries.

Ber Oomen

Executive Director - European Specialist Nurses Organisation (ESNO)

In 2005 he was co-founder of the European Specialist Nurses Organisations and since April 2018 Executive Director. In his position he is responsible for the overall management in expanding the network specialist nurses and advocating the role and position of specialist nurse in European context. In addition is active the EMA Health Professional Working Party, participate in Biosimilar working group and project leader of the Nurses Information and Communication Guide on Biosimilars and a variety of health issue projects such as Vaccination and AMR. In addition he is also a strong promoter of Continuing Professional Development and Life Long Learning during nursing lifespan career, has a personal passion for creative thinking, generate opportunities, and interconnect chances for nurses in European context. Nationality: Netherlands

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Anton Ussi

Operations & Finance Director, EATRIS

Anton Ussi (MSc) is Operations & Finance Director at EATRIS ERIC, the ESFRI landmark infrastructure for translational medicine. Joining EATRIS in 2010, he was responsible for the design and statutory incorporation of the infrastructure, whose membership counts 14 European Members States, and has been in his current role as executive director since 2015. Ussi has a background in technology transfer focused on molecular imaging, with previous history in mechanical engineering and automotive design, and small business administration. He specialises in public-private and public-public collaboration and translational research in medicine. Ussi is Principle Investigator of REMEDI4ALL, a large initiative developing a European medicines repurposing framework financed by the European Commission.

Lydie Meheus

Managing Director, Anticancer Fund

Lydie Meheus is Managing Director of the Anticancer Fund, a Belgian Research Foundation of Public Utility with an international scope. Lydie is member of the Advisory Board of OvaCure, Copenhagen and of Consilium-Scientific, London. She is part of the Steering Committee of 'Cancer research for more patient value', a fund managed by King Baudouin Foundation. She is member of the Cure Drug Repurposing Collaboratory, US and the Repurposing Observatory Group, Europe. She obtained a PhD in Sciences in 1986 (University of Ghent). She worked as head of different research groups and as VP R&D at Belgian biopharmaceutical companies.

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Christelle Bouygues

Regulatory Affairs Senior Officer, European Medicines Agency (EMA)

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. She was involved in particular with the implementation of the paediatric and pharmacovigilance legislation, and she is currently coordinating the implementation of the MDR/IVDR within EMA. Before joining the Agency, she 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.

James Burt

Vice-chair of the VAM Sector Group and CEO Pharmanovia

James joined Pharmanovia in October 2021 as CEO. Previously he served as the Executive Vice President EMENA at Accord Healthcare and oversaw branded and generic pharmaceutical activities across 65 markets for around a decade. Prior to this, he was Vice President for the Global Hospital Business at Actavis, responsible for the strategic direction of secondary-care activities worldwide. James has been an active participant in Medicines for Europe for most of the last 15 years. He holds a PhD in Chemical Engineering from the University of Birmingham, with a particular focus on biopharmaceutical manufacturing.

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Dunja Huijbers

Senior Programme Manager Rational Pharmacotherapy, ZonMw

Dunja Huijbers MSc is Senior Programme Manager Rational Pharmacotherapy at ZonMw, the Dutch Organization for Health Research and Development. ZonMw works on improving prevention, healthcare and health by encouraging and funding research, development and implementation. Dunja joined ZonMw in 2020 and is responsible for the national Drug Repurposing Programme. She manages programme operations and further develops the programme in dialogue with the Dutch Ministry of Health and other relevant stakeholders. Furthermore she is involved in the REMEDI4all project as (interim) work package leader aiming to connect and innovate Drug Repurposing research funding. Before joining ZonMw, she worked in different R&D roles within Pharma and CRO industry for 20 years and was involved in e.g. clinical trial start-up, project management and had leadership roles in the Nordic and Benelux countries.

Klára Marton

Vice-Chair of the Value Added Medicines Sector Group

Dr. Klára Marton is the Business Development Director of Egis Pharmaceuticals PLC /Servier Group/, one of the top branded generic pharmaceutical companies in the CEE and CIS regions. Her priorities at Egis is leading international strategic business development, defining mid- and long-term pipeline consists of value-added products, branded generics, biosimilar products, and digital patient solutions. She is also responsible for strategic licensing-in partnerships and alliance management. Under her leadership the early involvement of customer insight in business development, especially patient insight has been established. She is leading the Digital Patient Solutions HUB. Before Egis, she worked as Business Unit Director with responsibilities ranging from marketing, sales to market access covering several therapeutic areas at originator companies. She is a Medical Doctor holding a Master of Business Administration degree.

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Zoltán Kaló, PhD

Semmelweis University, Syreon Research Institute

Zoltán Kaló is a Professor of Health Economics at the Center for Health Technology Assessment (HTA) of Semmelweis University in Budapest, where he is leading a PhD program in HTA. Before moving to Semmelweis University in July 2019 he was the founder and co-director of an international MSc in Health Policy, Planning and Financing program at Eötvös Loránd University (ELTE). Dr. Kaló is also the founder and leader of Syreon Research Institute, an international research corporation specializing in health policy, health economic modeling and technology assessment. He has 25+ years of international experience in academia and industry, specializing in health systems design, HTA implementation, health economics and outcomes research, patient access and pricing policies of healthcare technologies. Dr. Kaló serves as a policy advisor to public decision-makers, global health care corporations and scientific societies. Between 2016-2021 he was a Scientific Committee member of the Innovative Medicines Initiative (IMI), the largest public-private partnership of the European Union in the field of health care innovation. He was a Director and Board Member of ISPOR (the Professional Society for Health Economics and Outcomes Research) between 2012-2014 and received the Marilyn Dix Smith Leadership Award of ISPOR for his contribution to the society in 2021. Selected list of publications: https://www.ncbi.nlm.nih.gov/myncbi/zoltan.kalo.1/bibliography/public/

Aurelio Arias

Director, EMEA Thought Leadership, IQVIA

Aurelio creates topical and forward-looking strategic content relevant to pharma executives worldwide and publishes articles, blogs, and white papers on a regular basis. Aurelio's predominant focus is on off-patent markets where he generates evidence-led insights with a view to spark high-level discourse on biosimilars, generics and value added medicines.

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María Álvarez Fernandez

Regulatory Affairs Coordinator, Spanish Generic Medicines Association (AESEG)

María Álvarez joined AESEG (Spanish Generic Medicines Association) in January 2020 as Regulatory Affairs Coordinator, to be in charge of technical departments at the association, including the areas: Regulatory Affairs, Pharmacovigilance and Quality. In this position, she is responsible for coordinating the regulatory and scientific activities at local level and she is also responsible for the coordination of several internal Committees and Working Groups. Prior to joining AESEG, María Álvarez was working a decade in leadership roles on Bausch & Lomb, first on the Regulatory Affairs area but also as Technical Director and Pharmacovigilance responsible, specialized on the national application of all areas. Currently, María is also member of the Board of SEVeM and she is also a member of the Regulatory Affairs and VAM groups from Medicines for Europe. María is qualified as a pharmacist at the University Complutense of Madrid, and she received her master's degree on Pharmaceutical Industry at CESIF.

Mariangela Rulli

Head of Public Affairs Area and autonomous groups IBG / VAM, Egualia

Head of Institutional Relations and coordination of IBG and VAM Autonomous Groups at EGUALIA - Industrie Farmaci Accessibili (formerly Assogenerici) the official representative body of the generic, biosimilar and Value-Added medicines industry in Italy, which brings together, under its umbrella, about 60 pharmaceutical companies, both small and medium-sized companies and multinationals. Law Graduate and specialized in Institutional Relations, Lobby and Corporate Communication. She has been working in Institutional Relations and Communications since 2015, working for different organizations and covering roles in increasing responsibilities. Before joining EGUALIA, she was a consultant at Comin & Partners, one of the major communications and lobbying firms in Italy, where she was responsible for building public affairs strategies for large clients in the healthcare, telecommunications, technology innovation, tobacco and automotive sectors. Between 2016 and 2018, she worked in the pharmaceutical company Roche, where she was involved in the implementation and management of various reputation building, stakeholder engagement, institutional communication, advocacy, and lobbying projects both for the company and the Foundation.

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James F O'Mahony

Research Assistant Professor, Centre for Health Policy and Management, Trinity College Dublin, Ireland

James is a Research Assistant Professor at the Centre for Health Policy and Management at Trinity College Dublin. He is an economist by training and his research addresses cost-effectiveness analysis appraisal methods. His research interests include pharmacoeconomic reimbursement systems and their transparency. His has published on the topic of cost-effectiveness thresholds and their application to drugs and other interventions. This work aims to ensure there is sufficient balance between expenditure on drugs and non-drug interventions within health systems. James also works in the area of simulation modelling of cancer screening and is a member of Ireland's National Screening Committee.

Guilherme Safioti

Senior Director Global Medical Affairs, Digital Respiratory, Teva

Guilherme Safioti is a pulmonologist and Sr Global Medical Director at Teva Pharmaceuticals. For the past 6 years he's been working in Teva Pharmaceutical's Digital Respiratory program, together with a large cross-function team. This program has led to the FDA-approval of the world's first integrated electronic inhaler device, providing objective information about the frequency and quality of inhalation via a mobile app, empowering the patients to take an active role in their health management. His research focuses on the effectiveness of digital therapeutics to improve clinical management and outcomes for asthma and COPD patients, as well as in the development of machine-learning algorithms to predict exacerbations. Besides airway diseases and digital health, Guilherme is interested on aerosol therapy, patient adherence, behavior and complex interventions. He received his medical degree from Faculdade de Medicina de Ribeirão Preto (USP), Brazil, followed by residency in Respiratory Medicine at Hospital das Clínicas de Ribeirão Preto, Brazil. Guilherme is a member of the Swedish Respiratory Medicine Association and the European Respiratory Society.

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Nicolas Sireau

Chair of Trustees at the AKU society & Co-founder and Chairman Beacon

Nick Sireau, PhD, is the CEO and Chair of Trustees at the AKU Society, a patient group that helps people with AKU, a rare genetic disease affecting two of his children. The AKU Society and Nick are the winners of the 2021 Members Award by EURORDIS (the European Organisation of Rare Diseases) because of their work on successfully developing a new treatment for AKU. Nick is co-founder and Chair of Beacon, an organisation that helps all rare disease patient groups. He is the editor of 'Rare Diseases: Challenges and Opportunities for Social Entrepreneurs' (Greenleaf 2013) and of the 'Patient Group Handbook: A Practical Guide for Research and Drug Development' (Beacon 2016). Nick is co-founder and Chair of Orchard OCD, a medical charity that funds research into obsessive-compulsive disorder (OCD), a common yet debilitating mental health condition. He is also co-founder of Sirgartan Therapeutics, a biotech that focuses on new treatments for OCD. Nick has a BA from Oxford University, an MSc in management studies from the Lyon Graduate School of Business and a PhD in social psychology from City University. He is a fellow of the Ashoka Fellowship of Social Entrepreneurs.

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.

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Florian Schmidt
Deputy-Head Unit D1, DG Sante European Commission

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

Kristof Roox
Partner, Crowell & Moring LLP

Kristof Roox is co-managing partner of Crowell & Moring's Brussels Office. He is a partner in the Intellectual Property Group and focuses on IP litigation, and in particular on complex patent litigation in the life sciences sector. With nearly 30 years of experience, Kristof has an impressive reputation before the Belgian civil and administrative courts, and before regulatory authorities. He is also widely respected for his pragmatic and creative approach to solving business disputes and for his to-the-point counselling. In addition to traditional IP litigation and counselling, Kristof is widely recognized for his thought leadership in relation to the regulatory aspects of life sciences. He advises companies and trade associations on launch and marketing strategies, parallel imports, promotional practices, rebates, pricing and reimbursement, distribution models, OTC products, health care reforms, competition law aspects, etc. Furthermore, Kristof is an experienced litigator across a broad range of commercial and civil matters, covering all aspects of dispute resolution including arbitration. With his deep knowledge of private international law issues, he often tackles complex multi-jurisdictional questions and he is reputed for his broad knowledge of procedural law issues.

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Momir Radulović

Executive Director, Slovenian Medicines and Medical Devices Agency, European Medicines Agency Management Board Member

Momir Radulović leads the Slovenian Medicines and Medical Devices Agency since Dec 2018. He is a member EMA MB, a member of EC Pharmaceutical Committee, a member HMA MG. He led Slovenian Presidency of the Council of the EU 2021 in the area of medicines and one of the topics was repurposing of medicines – the underrated champion of sustainable innovation. He continues with repurposing as STAMP member, member of Critical Path Institute, Regulatory Policy and Legislative Group member and REMEDi4ALL Policy Board member 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.

Maja (Sercic) Graf

Associate Director Policy & Market Access, Medicines for Europe

Maja (Sercic) Graf 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.

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