



THE HOTEL, BRUSSELS 7 NOVEMBER 2023

# **Speakers, Chairs and Panellists**



#### 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.



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

Cristina Montané, 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, Citizen Participation Director of the Foro Español de Pacientes (FEP), Territorial Coordinator and Patient Advocate of ACAF -Catalan Association of People Affected by Fibromyalgia and Chronic Fatigue Syndrome, Secretary of the FM-SFC-SQM Family Platform, and Member of the Management Committee of the Patient Experience Observatory of Hospital Clinic Barcelona.



#### Adrian van den Hoven, Director General, Medicines for Europe

Adrian van den Hoven has been director general of Medicines for Europe since September 2013. In his role he focuses on stimulating competition in off-patent medicine markets, fostering access to medicine, reducing medicine shortages and addressing major health crises, supporting policy measures for sustainable pricing, promoting efficient regulatory standards, and developing a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value-added medicines industries. He is also member, and former president, of the European Medicines Verification Organization (EMVO) board for the implementation of serialization against falsified medicines, the vice-chair of the International Generic and Biosimilar medicines Association (IGBA) and a member of the joint industry advisory council of the Health Emergency and Response Authority (HERA).









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## Julia Schmitz, Policy Officer, Unit D1, DG Sante European Commission

Julia Schmitz is a Policy Officer in the European Commission's Directorate-General for Health and Food Safety (Unit SANTE.D1), where she is part of a team working on pharmaceutical policy and legislation. In her previous positions at the European Commission, she dealt with health technology assessment and health research policy. Before joining the Commission, she worked in the German public service and at the World Health Organization. Her background is in biomedical science and public health.



### Antonella Cardone, CEO, Cancer Patients Europe

Antonella Cardone is currently the CEO of Cancer Patients Europe, the pan-European and all-cancer types patient association. She is the Patient Advocacy Expert and Advisor to the Board of Pancreatic Cancer Europe (PCE), the European Multi-Stakeholder Platform of leading and most influential groups of physicians and patients, politicians, journalists, academia, and industry on Pancreatic Cancer. She is the former Director of the European Cancer Patient Coalition (ECPC). She has 25 years of experience working for non-profits in the health, social, and employment sectors. Prior to ECPC, Antonella was the Executive Director of the Fit for Work Global Alliance, a multi-stakeholder coalition championing change in health and work policy. She has previously served as the Director of the Global Smoke-free Partnership of the American Cancer Society, leading a movement of over 100 members to coordinate the development of smoke-free laws in 40 countries. She holds a Master's in Science and one in Business Administration. She represented ECPC on the Board of All.Can and on the Board of Pancreatic Cancer Europe, in which she was vice-chair.











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#### Nóra Gyimesi, PharmD, Msc, Chair of pre-filled syringes Special Interest Group, EAHP

Nóra Gyimesi a pharmacist specialised in clinical pharmacy and infectology. She holds a degree in health policy and financing. She works as a hospital chief pharmacist in Hungary. She is member of board of the Hungarian Chamber of Pharmacists and member of pharmacoeconomy workgroup of the Society of Hospital Pharmacy in Hungary. She is the chair of Special Interest Group on Prefilled Syringes of the European Association of Hospital Pharmacists. She works on topics including evaluation and implementation clinical pharmacy services, drug-utilisation studies and procurement.



### Hans Platteeuw, Executive Director, Galenicap

Hans Platteeuw holds a M.Sc. degree in Chemistry and straight after graduating started working as a Pharmaceutical Product Developer at Intervet (The Netherlands), Synthon B.V. (The Netherlands) and Dafra Pharma (Belgium). In 2005 he started his own consultancy and product development company called Avivia (The Netherlands), which has grown to a full fledged Contract Research Organisation with its own lab facilities. Through Avivia he has played a pivotal role in product development projects in New Chemical Entities, Generics and Value added Medicines for many companies from Big Pharma to small spinoffs of Universities. His most important asset is a combination of an entrepreneurial mindset with a deep understanding of the science and this brings innovative but practical solutions to any challenge. Currently, Hans is acting as the Chief Scientific Officer of Galenicap (www.galenicap.com). Galenicap acts as an incubator to turn academic clinical concepts into pharmaceutical products that are ready for industry.



Raluca Radu, Value Added Medicines Policy Manager, Medicines for Europe

Raluca works currently as a Value Added Medicines Policy Manager at Medicines for Europe. In her current role she combines her scientific background from her training as a pharmacist, with her passion for health and regulatory









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policy. In her daily work Raluca focuses on advocating for policies which create a supportive environment for innovation in the off-patent space, allowing us to capitalise on the full potential of existing medicines, and shift to a more sustainable drug development pathway.



#### 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. She is currently coordinating the EU repurposing pilot and 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.



## Patricia Vandamme, Policy Officer, Anticancer Fund

Patricia Vandamme is Policy Officer at the Anticancer Fund. She has been working more than 20 years in the pharmaceutical industry, both in Belgian and global roles, before joining ACF in 2022. She is highly skilled in regulatory affairs, pharmacovigilance and quality assurance. As a pharmacist she is fully committed to the health and wellbeing of patients. She plays an important role in connecting with peer organizations, clinical investigators, drug developers and policymakers to make sure drug repurposing makes a leap forward in oncology, as cancer patients urgently need more costly-effective treatments options.











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#### Heleen van der Meer, Senior Programme Manager International Drug Repurposing, ZonMw

Heleen van der Meer (Pharm D, PhD) is a senior programme manager on international drug repurposing 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. On behalf of ZonMw, Heleen is workpackage leader in the EU-project REMEDi4ALL - the research initiative that is building a sustainable European innovation platform to enhance the repurposing of medicines for all. In REMEDi4ALL she has the lead in creating a funders network and 'think tank' with the aim to discuss policy issues, share best funding practices, co-ordinate (new) funding streams, promote joint calls and develop innovative co-funding models for drug repurposing. Heleen is a pharmacist and holds a PhD in the field of pharmacotherapy and -epidemiology in older people. She has worked as a pharmacotherapy advisor at the Dutch HTA organisation for a couple of years before she joined ZonMw in 2022.



#### Vaibhav Sharma, Head of Value Added Products, Zentiva

Vaibhav has 15+ years in pharmaceutical industry with experience in various roles and diverse geography. For the past 4 years, he is head of value added products for Zentiva, and is responsible and accountable for the identification of value added products (or improved originals), and bringing them to Europe market, with the help of cross-functional teams including internal experts as well as advice of external experts".









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#### 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 priority at Egis is leading international strategic business development, defining mid- and long-term pipeline consists of value-added products, commodity generics, biosimilar products, and digital patient solutions. She is also responsible for strategic partnerships, licensing-in and alliance management. She is leading the ideation process for Egis R&D. Under her leadership the early involvement of customer insight in business development, especially patient insight has been established. Digital Patient Solutions HUB is part of the BD team. Before Egis, she worked as Business Unit Director with responsibilities ranging from commercial, marketing, sales to market access covering several therapy areas at different multinational companies.



### Aurelio Arias, Director, IQVIA Thought Leadership

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.



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

Maja 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









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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.



## Zsuzsanna Petykó, Researcher, Center for Health Technology Assessment, Semmelweis University and **Health Economist, Syreon Research Institute**

Zsuzsanna Petykó MD MSc is a medical doctor and health economist. She joined Syreon Research Institute in 2018 and she has been managing several research projects in the field of health technology assessment of special health technologies (pharmaceutical and non-pharmaceutical) with particular interests in drug repurposing, diagnostic imaging and digital health solutions. She also started her PhD studies in 2019 at Semmelweis University in the Center for Health Technology Assessment, her doctoral research project has a special focus on the value assessment frameworks of value-added medicines and repurposed drugs. Since 2022 - as the project manager from Syreon's side - she has been actively involved in the 5-year long, EU Commission-funded project, REMEDi4ALL, that aims to build a sustainable European innovation platform to enhance the repurposing of medicines.



### Laurent Martin, Chief Pharmaceutical Affairs Officer, ORPHELIA Pharma

PharmD with a Master in Public Health Law and a Master in Business Administration. 30 years' experience in the pharmaceutical and biotechnology industry though leading functions in international Regulatory/Pharmaceutical Affairs & Drug Development. Main areas of expertise include paediatric and orphan drug development. As Chief Pharmaceutical Affairs Officer, Laurent Martin oversees the European regulatory activities though commercialisation of ORPHELIA Pharma's paediatric and orphan medicinal products pipeline in oncology and neurology. Prior to joining ORPHELIA Pharma 4 years ago, Laurent Martin spent 12 years at DBV Technologies, his last position in this biotechnology company being Chief Development Officer, fousing on the development of a new treatment for paediatric food allergies. Earlier, Laurent Martin also successfully managed the international registration of several paediatric orphan medicinal products of Orphan Europe now Recordati Rare Diseases in the metabolic diseases area.









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## Pan Pantziarka, Director Drug Repurposing, Anticancer Fund

Dr Pan Pantziarka is Director of Drug Repurposing at the Anticancer Fund. Working on drug repurposing in oncology - from drug candidate identification to clinical trials to health policy work. Current projects include sarcoma clinical trials, engaging with regulators on specific repurposing projects in rare cancers and working as part of the REMEDI4ALL platform on regulatory and research funding issues. Member of the Executive Committee of FOSTER (Fight Osteosarcoma Through European Research). Chairman/co-founder George Pantziarka TP53 Trust – the UK organisation for people with Li Fraumeni Syndrome. Member of the steering committee of the Bone Sarcoma Alliance - an alliance of bone sarcoma patient advocates under the Sarcoma Patient Advocacy Global Network (SPAGN) umbrella.



#### James Burt, Vice-chair of the Value Added Medicines Sector Group and CEO Pharmanovia

James joined Pharmanovia in October 2021. 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. James is Vice-Chair of the Medicines for Europe, Value Added Medicines Sector Group.



Cesar Hernández García, Director General, Common Portfolio of the NHS and Pharmacy, Spanish Ministry of Health Dr. César Hernández MD, PhD. joined the Spanish Agency for Medicines and Medical Devices as a Head of the Human Medicines Department in 2009.











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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.



#### Susana Almeida - Clinical Development and Safety Director, Medicines for Europe

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.



## Andrej Segec, Scientific administrator, DARWIN EU® Project manager, Data Analytics and Methods Task Force, **European Medicines Agency (EMA)**

Andrej Segec is originally from Slovakia and a pharmacist by training (Comenius University, Bratislava, Slovakia) with an MSc in Epidemiology (London School of Hygiene and Tropical Medicine, London, UK). He has worked for the European Medicines Agency (EMA) since 2008, holding a number of roles in pharmacovigilance, from signal detection and signal management, monitoring of the performance of the EMA pharmacovigilance system, in surveillance and epidemiology, as committee manager for the operations of the Pharmacovigilance Risk Assessment Committee (PRAC) and as a risk management specialist for anti-infective therapies and vaccines during the COVID-19 pandemic. In the current role, Andrej's focus is on the generation and use of real world evidence in regulatory decision making and the establishment of the Data Analysis and Real World Interrogation Network (DARWIN EU®).



