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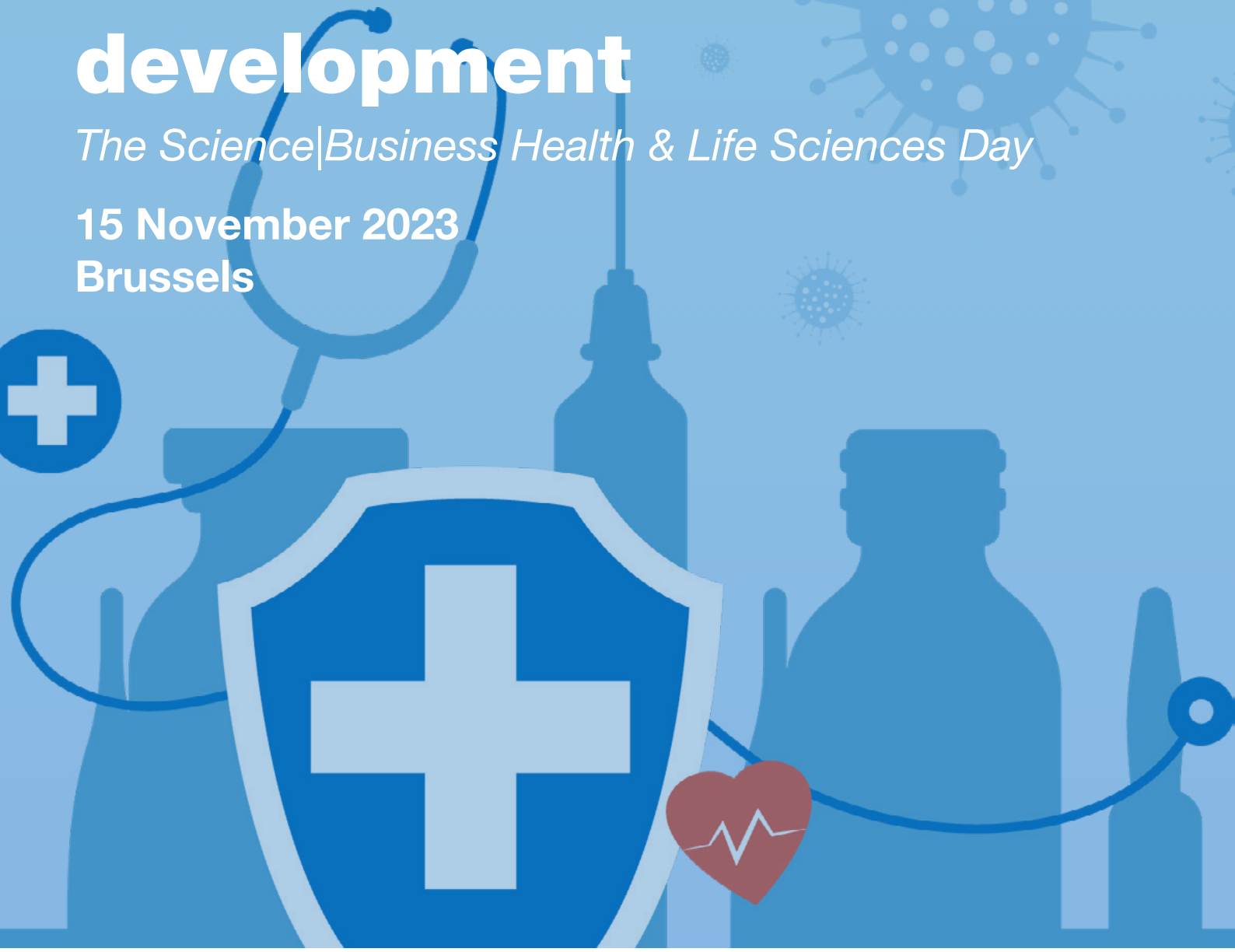
HEALTH SECTOR DAYS

Health innovation and the future of medicines development

The Science|Business Health & Life Sciences Day

15 November 2023
Brussels



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CONTEXT

In April this year, the European Commission issued its proposals for a comprehensive revision of the EU's basic pharmaceutical legislation. Reflecting key lessons learned from COVID, the proposals seek to create an "innovation-and competitiveness-friendly" landscape in Europe for biomedical research and medicines development, while ensuring greater resilience and autonomy in the event of future health crises and addressing the sector's environmental footprint.

Yet various R&D stakeholders are concerned that – in trying to strike a balance between a myriad of public and private sector interests – the Commission could inadvertently achieve the opposite. For example, shortening EU patent protection on new therapeutics is intended to boost patient access to medicines, but could persuade pharmaceutical companies, scientists and investors to prioritise other regions to develop and commercialise breakthrough innovations in the future. Under such a scenario, Europe's whole health and life sciences community is likely to feel the chill, with fewer resources over time to sustain its historical excellence in fundamental research, international cooperation platforms, and global scientific leadership. Both pharmaceutical and medical technology companies are closely watching the EU's actions on data sharing.

What ultimately emerges in terms of new directives and regulation will have a direct impact on pharmaceutical and medical technology R&D ecosystems everywhere – not just in terms of corporate investment and production planning, but also attractiveness to venture capital, public-private partnerships and top research talent, among others. And perhaps more importantly, it may influence Europe's readiness to provide global leadership – both scientific and political – when the world is confronted with its next urgent health crisis.

Therefore, health innovation and the future of medicine development is the central theme of this S|B Health & Life Sciences Day. We will explore the state of play at the interface between healthcare legislative and regulatory agendas and their R&D equivalents. The day features expert panel discussions and debates on specific challenges and opportunities that will influence the next era of research-industry collaboration, including issues such as data access and sharing across borders, and the wider implications for health and life sciences in Europe.

AGENDA

09:00 Welcome coffee and registration

09:30 Welcome by Simon Pickard, Network Director, Science|Business

09:35 For the greater good: How can regulatory frameworks foster breakthrough innovation in health and life sciences?

Plenary debate about the latest developments in negotiations around the Commission's proposals to revise the EU's general pharmaceutical legislation and the wider implications for HLS ecosystems, both in Europe and beyond.

- **Tomislav Sokol**, Member, European Parliament
- **Janina Dzambazoska**, Head Regulatory Affairs Europe, Novartis
- **Sol Ruiz**, Head of Biologics, Biotechnology and Advanced Therapies, Spanish Agency of Medicines and Medical Devices
- **Lilia Luchianov**, Policy Officer, Medicines: policy, authorization and monitoring, DG SANTE, European Commission
- **Arjon van Hengel**, Deputy Head of Unit, Health Innovations & Ecosystems, DG RTD, European Commission

Moderator: Simon Pickard, Network Director, Science|Business

10:30 Coffee and networking break

11:00 Parallel sessions – Strategic choices: Where should policy makers focus next? (Details can be found on the next page)

12:10 Impact pathways: Transforming the biotech ecosystem

Live Q&A with: **Hugues Bultot**, Chief Executive Officer, Univercells

12:30 Competitive balance: How will Europe be positioned by 2030?

A closing plenary discussion that explores the longer-term implications of the Commission's proposals at the interface between industrial competitiveness, trade policy and its R&D equivalent, and where that might leave Europe as a global actor in the decade to come.

- **Maja Fjaestad**, Expert Coordinator, Centre for Health Crises, Karolinska Institutet
- **Paul Csiszar**, Director, Markets and Cases IV: Basic Industries, Manufacturing and Agriculture, DG Competition, European Commission
- **Niklas Blomberg**, Director, ELIXIR
- **Robin Evers**, Senior Vice President for Submissions & Life Cycle Management, Novo Nordisk

Moderator: Maryline Fiaschi, CEO, ScienceIBusiness

13:15 Networking lunch

AGENDA

11:00 Parallel sessions

Strategic choices: Where should policy makers focus next?

Parallel panel debates on where Europe and international partners should prioritise R&I policy instruments and investments to increase the world's preparedness and resilience for future health crises. Indicative themes:

1/ Combat stations: Upscaling efforts to tackle antimicrobial resistance

According to the World Health Organization, antimicrobial resistance (AMR) is an urgent public health and economic challenge, and good quality research is a vital part of the response. This session explores what is needed to effectively drive the development of a robust and sustainable R&D pipeline for novel antimicrobials.

- **Andrea Chiarello**, Head of EU Government Affairs, Pfizer
- **Ingrid Wanninger**, Board Member, BEAM Alliance and Managing Director, HYpharm GmbH
- **Olivier Mignolet**, Partner, Simmons & Simmons
- **Reinhilde Veugelers**, Professor, Faculty of Economics and Business, KU Leuven

Moderator: Brandon Mitchener, Senior Advisor, Science|Business

2/ Forewarned is forearmed: Can industry-research alliances prepare us for the next pandemic?

An unprecedented level of cross-sector, cross-border scientific cooperation underpinned the world's response to COVID. Can policy, science and business agree on a strategic R&I agenda to mitigate future crises, and if so, what should be at the top of the list of research and technological priorities?

- **Sarah Garner**, Senior Policy Advisor, Access to Medicines & Health products, Division of Country Health Policies and Systems, World Health Organisation Europe
- **Clément Williamson**, Political Assistant to the Director-General, Health Emergency Preparedness and Response Authority (DG HERA), European Commission
- **Paul Kellam**, Professor of Virus Genomics, Department of Medicine, Imperial College London; CSO, RQ Biotechnology Ltd, UK
- **Magda Krakowiak**, Director of Business Creation, EIT Health
- **Roberto Bruzzone**, Professor, Institut Pasteur, Paris; Co-Director, Centre for Immunology & Infection, Hong Kong

Moderator: Florin Zubascu, Executive Editor, Science|Business

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For the greater good: How can regulatory frameworks foster breakthrough innovation in health and life sciences? (Opening plenary)

FEATURED GUESTS

Janina Dzambazoska, Head of Region Europe Regulatory Affairs, Novartis

Janina Dzambazoska is a regulatory professional with over 20 years of experience in global regulatory strategy in both innovative medicines and biosimilars and in multiple therapy areas. She also has hands on experience with multiple EMA and FDA regulatory procedures across the full life cycle of the medicinal product, from obtaining development advice, orphan designations, pediatric investigational plans, clinical trials applications, to marketing authorization application and subsequent life cycle management of the medicinal product. She is a pharmacist by training and started her professional experience in a community pharmacy in 1998.

Arjon van Hengel, Deputy Head of Unit, Health Innovations & Ecosystems, DG RTD, European Commission

As deputy head of unit, Arjon van Hengel fosters the development and uptake of breakthrough innovations in the field of health and care and helps citizens stay healthy in particular through health-promoting environments and people-centered healthcare systems. He has been at the Commission since 2005 and worked on various aspects of health-related research. He was team leader for infectious diseases during the first part of the COVID-19 pandemic, a policy officer for antimicrobial resistance and has led a research group that develops and validates analytical detection methods for food allergies. He holds a PhD in Molecular Biology.

Lilia Luchianov, Policy Officer, Medicines: policy, authorization and monitoring, DG SANTE, European Commission

Lilia Luchianov has been working in the field of pharmaceuticals for more than a decade. She has also contributed to handbooks such as " EU Law of Competition and Trade in the Pharmaceutical Sector", has been a lecturer on competition and intellectual property law at the University of Strasbourg, and has shared her knowledge in many presentations to other professionals.

Sol Ruiz, Head of Biologics, Biotechnology and Advanced Therapies, Spanish Agency of Medicines and Medical Devices

Sol Ruiz has been a co-opted member of the Committee for Human Medicinal Products (CHMP) since 2007 and is currently a member of the Committee for Advanced Therapies (CAT). Prior to this, she chaired the Biologics Working Party at te European Medicines Agency (EMA) from March 2014 to February 2023. She holds a PhD in biology, specializing in immunology.

Tomislav Sokol, Member, European Parliament

Tomislav Sokol has been a member of the European Parliament since 2019. He is the main rapporteur for the European Health Data Space and EPP shadow rapporteur for pharmaceutical legislation. He is also EPP coordinator in the Committee on Public Health, EPP vice-coordinator in the Special Committee on the COVID-19 pandemic and member of several other committees in the European Parliament. Previously he was a member of the Croatian Parliament and an assistant minister in the Ministry of Science and Education. He holds a degree in law at the University of Zagreb and both a master of law and PhD from the Katholieke Universiteit Leuven.

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Combat stations: Upscaling efforts to tackle antimicrobial resistance

FEATURED GUESTS

Andrea Chiarello, Head of EU Government Affairs, Pfizer

Andrea Chiarello joined Pfizer in 2015. In his current role, he is responsible for driving Pfizer's EU external engagement strategy and managing relationships with Brussel-based trade associations. His focus is on AMR policy at the EU level and he chairs EFPIA's AMR Working Group. He holds a master's degree in EU Diplomacy from the College of Europe, as well as a master's in EU Policies from Padua University

Oliver Mignolet, Partner, Simmons & Simmons

Olivier Mignolet is Simmons & Simmons' country head for Belgium and leads the Belgian dispute resolution practice. He has gained significant experience in advising and representing companies in the healthcare and life sciences sector. He represents and advises industry clients from Top 10 global pharmaceutical and medical devices companies to Belgian biotechs, and trade associations. He has also been a part-time lecturer at the University of Louvain for 12 years. He and has also edited and co-authored a two-volume book on European and Belgian pharmaceutical law.

Reinhilde Veugelers, Professor, Faculty of Economics and Business, KU Leuven

Reinhilde Veugelers is a full professor at the Department of Management, Strategy and Innovation at KU-Leuven in Belgium. She has been a senior fellow at Bruegel since 2009 and a senior non-resident fellow at the Peterson Institute for International Economics since 2020. Moreover, she is currently a member of the Board of Reviewing Editors of the journal Science and a Co-PI of the Science of Science Funding Initiative at the National Bureau of Economic Research.
Veugelers is an expert in industrial organisation, international economics, strategy, innovation and science.

Ingrid Wanninger, Board member, BEAM Alliance; Managing Director, HYpharm GmbH

Ingrid Wanninger is responsible for developing the innovative product portfolio of HYpharm in the areas of AMR, infectious diseases and prevention of infections using state-of-the art technology in public-private partnerships. Since 2023 she has also been active as an elected officer in the Board of BEAM Alliance. She has over 20 years of experience in the biotech and pharmaceutical industry as well as the public sector. Areas of focus include infectious diseases, protein biochemistry and immunology.

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Forewarned is forearmed: Can industry-research alliances prepare us for the next pandemic?

FEATURED GUESTS

Roberto Bruzzone, Professor, Institut Pasteur, Paris; Co-Director, Centre for immunology & Infection, Hong Kong

Roberto Bruzzone joined the Institut Pasteur in 1995 where he is a professor in the Department of Cell Biology and Infection. In 2006 he moved to Hong Kong, where he has been co-director at the HKU-Pasteur Research Pole, with a joint appointment as visiting professor at the University of Hong Kong. He has been the chair of the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) since 2020, and the founding co-director of the Centre for Immunology at the Hong Kong Science Park. He studied medicine at the University "La Sapienza" in Rome, where he graduated in 1980. Later he did postgraduate work at the University of Geneva and Harvard Medical School.

Sarah Garner, Senior Policy Advisor, Access to Medicines & Health products, Division of Country Health Policies and Systems, World Health Organisation Europe

Sarah Garner is a pharmacist specialising in global access issues and responsible for the strategic planning and delivery of ministerial policy dialogues and technical support to improve patient access in the WHO European Region. Before, she coordinated a team in the Essential Medicines and Health Products Department at WHO HQ, was the associate director for Science Policy and Research at the UK's National Institute for Health and Care Excellence, and pharmacist lead for the UK Government's Special Advisory Committee on Antimicrobial Resistance. She was also the technical lead for the Oslo Medicines Initiative and led policy work packages of public-private research partnerships.

Paul Kellam, Professor of Virus Genomics, Department of Medicine, Imperial College London; CSO, RQ Biotecnology Ltd, UK

Paul Kellam's research identified how HIV develops resistance to antiviral drugs and identified the first influenza disease severity gene in people hospitalised with influenza virus. His laboratory produced the virus genome analysis of the MERS CoV outbreaks and contributed to the international Ebola virus genome analysis to show the factors influencing virus transmission. His work on B cell repertoires applies genetics and computational biology to discover antibodies to prevent infections. He was also the scientific advisor to the UK's COVID-19 Vaccine Task Force.

Magda Krakowiak, Director of Business Creation, EIT Health

As director of EIT Health Accelerator, Magda Krakowiak leads a diverse and international team, driving business acceleration and innovation initiatives supporting approximately 200 European healthcare start-ups each year. Her professional focus lies on fostering needs-driven innovation, aiming to create solutions that positively impact patients and society. Her academic background includes a master of arts in law from the University of Warsaw, a master in history from the University of Opole and specialized AI in healthcare training from MIT Sloan School of Management.

Clément Williamson, Political Assistant to the Director-General, Health Emergency Preparedness and Response Authority (HERA), European Commission

Clément Williamson has been at the European Commission since 2006. He joined DG SANTE for the handling of the COVID-19 crisis and the creation of HERA, where he is currently assisting the Director-General. He has previously held a various other positions in the European Commission, from support to research, space observation and support to small businesses. He was also a part of the team negotiating the latest multiannual EU budget. Before joining the European Commission he worked in the aerospace sector.

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FEATURED GUESTS

Impact pathways: Transforming the biotech ecosystem.

Hugues Bultot, CEO and Co-Founder, Univercells

As founder and CEO of Univercells since its establishment in early 2013, Hugues Bultot has led the company's advancement in all activities related to business ventures. He brings more than twenty years of expertise as CEO and serial entrepreneur in the life sciences and biotehnology industries to the global team of experts at Univercells Group. He holds a master's degree in law from UCL Belgium, and executive master's degree in business administration from Solvay Business School, in tax management from ICHEC BElgium, and a certification in innovation from MIT's Sloan School of Management in the United States.

Competitive balance: How will Europe be positioned by 2030?

Niklas Blomberg, Director, ELIXIR

As the founding director of ELIXIR, Niklas Blomberg has been with the organisation since 2013 and has led its development into a key part of large European initiatives such as the European Genomics Infrastructure, the European Open Science Cloud, and the European Health Data Space. Before joining ELIXIR, he worked in pharmaceutical R&D for AstraZeneca. He holds a PhD in structural bioinformatics and protein nuclear magnetic resonance spectroscopy from the European Molecular Biology Laboratory in Heidelberg and a bachelor of science in biochemistry from Göteborg University, Sweden.

Paul Csiszár, Director, Markets and Cases IV, Basic Industries, Manufacturing and Agriculture, DG Competition, European Commission

Prior to joining the European Commission, Paul Csiszár practiced as a corporate, securities and M&A lawyer in the US, in Europe with the international law firm of Squire Sanders and later in the public sector. He holds a degree from ELTE School of Law of Budapest and Loyola Law School in the United States, where he studied international comparative law and earned a second juris doctorate.

Robin Evers, Senior Vice President for Submissions & Life Cycle Management, Novo Nordisk

Robin Evers is a senior executive within the research & development leadership at Novo Nordisk. He is experienced in building patient-centered innovative product development strategies and managing portfolios of products across multiple therapeutic areas. At Novo Nordisk, he has initiated transformational change activities supporting bolder, more agile development and reducing time to market. He has over 25 years' experience in pharmaceutical development including in regulatory and global medical affairs, pharmacovigilance, and quality assurance. He has worked closely with trade associations, including in his role as chair of EuropaBio Healthcare Council.

Maja Fjaestad, Expert Coordinator, Centre for Health Crisis, Karlinska Institutet

Maja Fjaestad is affiliated to research at the Department of Learning, Informatics, Management and Ethics (LIME) at Karlinska Institutet. She is the expert coordinator in the field of policy and preparedness at the Centre for Health Crises and also holds a position as senior advisor at AI Sweden. Her research focuses on the interaction between health, society, technology and values in AI and on crisis management. Prior to joining Karlinka Institutet, she was state secretary for Healthcare to the Government of Sweden and held an associate professorship at the Royal Institute of Technology (KTH).

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MODERATORS

Maryline Fiaschi, CEO, ScienceIBusiness

Maryline Fiaschi joined Science|Business in 2011. Appointed managing director in 2016 and CEO in 2021, she leads the company's operations and growth strategy. Previously, she managed EU education programmes with the European Commission for six years, before entering the media business in 2007.
She held business development positions at Shanghai Daily and EU affairs media company EurActiv. She is also an external evaluator for several EU higher education and research and innovation programmes. Maryline holds degrees from Université La Sorbonne, Università di Bologna and Université de Louvain.

Brandon Mitchener, Senior Advisor, Science|Business

Brandon Mitchener is a former correspondent of 15 years for The Wall Street Journal, International Herald Tribune and Dow Jones Newswires in Germany and continues to write about EU policies, science, research and other topics. Since 2004, he has also been actively helping people and organisations communicate better and make better public policy decisions through strategic advice and campaign management. He has advised companies, business associations and non-governmental organisations in a wide variety of sectors including agriculture, food, energy, health and transportation.

Simon Pickard, Network Director, Science|Business

Simon leads on network engagement and development for Science|Business in line with the company's growth strategy. He previously held directorial positions with The Academy of Business in Society (ABIS) network and IDAS Global, a technology solutions provider to the global cash industry. Within these roles, he designed and coordinated a wide range of international projects focused on sustainability-driven innovation, both in research and education. Simon holds a Masters Degree from the University of Oxford and an MBA from HEC Paris School of Management.

Florin Zubascu, Executive Editor, Science|Business

Florin is Executive Editor, leading Science|Business news coverage on research and innovation policy in Europe. He is covering EU R&D policy, the Horizon Europe programme, Europe's innovation divide and R&D policy reforms in central and eastern Europe. He managed the Science|Business newsletters since 2014 and, in 2017, he helped implement a complete redesign of www.sciencebusiness.net. Previously, Florin worked as a political science researcher and web producer for various organisations and think-tanks in Romania and Hungary. He holds degrees in political science from Central European University in Budapest and Babeș-Bolyai University in Cluj-Napoca.

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