



UCD Sutherland School of Law



Report of the COMPHACRISIS Project Final Workshop

Dr Mina Hosseini

September 2024

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Healthcare at the Crossroads: COMPHACRISIS Workshop on Regulation, Innovation, and Market Dynamics

MSCA Workshop

13 September 2024

UCD Sutherland School of Law

<u>The Sutherland School of Law</u> at <u>University College Dublin (UCD)</u> hosted a one-day workshop entitled "Healthcare at the Crossroads: COMPHACRISIS Workshop on Regulation, Innovation, and Market Dynamics" on 13 September 2024. The workshop brought together academics, competition, business and law scholars, researchers, postgraduate students, practitioners and law enforcers to discuss the complex interplay between healthcare regulation, market dynamics, competition and innovation in the European context.

The workshop commenced with an opening welcome and overview provided by <u>Professor Imelda Maher</u>, the Sutherland Full Professor of European Law and Director of the <u>Dublin European Institute</u>.



Professor Maher set the stage for the day's proceedings, outlining the workshop's objectives and the significance of examining healthcare regulation, competition innovation, and market dynamics in the current European landscape. Additionally, she provided an overview of Dr Mina Hosseini's activities and her COMPHACRISIS project over the past two years, highlighting the research and insights that have emerged from this initiative focused on EU Competition law and policy in the pharmaceutical sector across normal, crisis, and post-crisis periods. The workshop was structured into two main panel sessions, each focusing on critical aspects of healthcare regulation and market dynamics.

The first panel, chaired by <u>Professor Suzanne Kingston</u> of UCD and the General Court of the European Union, addressed "Competition in EU Healthcare Sector: Hospitals and Pharmaceutical Markets." This session featured presentations from <u>Dr Mary Guy</u> of Liverpool John Moores University and <u>Dr Diletta Danieli</u> of the University of Verona, with <u>Dr Vincent Power</u> from A & L Goodbody as the discussant.

Dr Guy presented "On The Quiet Power of National Decisions: Hospitals, State Aid, and Services of General Economic Interest." Her talk explored the complex relationship between EU competition law and national healthcare systems, focusing mainly on state aid cases regarding hospitals.



She discussed the recent developments in this area, including the 2022 European Commission review of the Services of General Economic Interest (SGEI) exception mechanism in healthcare and the 2023 Court of Justice of the European Union judgment in the Casa Regina Apostolorum case.

In the second presentation of the first panel, Dr Danieli focused on "Regulatory exclusivities in the revised EU pharmaceutical legislation: revisiting the balance between innovation and competition." Her talk provided an insightful overview of the changing legislative framework in EU pharmaceutical regulation, including the European Health Union initiative, the Pharmaceutical Strategy for Europe, and the recent revision of EU pharmaceutical legislation.



Dr Danieli highlighted critical aspects of the proposed Directive and Regulation, emphasising the revised balance in the regulatory data protection system and introducing new incentives, such as the transferable data exclusivity voucher (TEV) for priority antimicrobials. She also discussed the interplay with other ongoing reforms, including new compulsory licensing instruments for crisis management and the recast of existing regulations governing supplementary protection certificates.

In his role as discussant for Panel 1, Dr Vincent Power provided insightful commentary on the presentations by Dr Guy and Dr Danieli. Drawing on his extensive experience in EU competition law, he addressed the complex interplay between national decisions on healthcare services and EU-level competition law, noting the significant implications of recent cases such as Casa Regina Apostolorum.



The second panel, chaired by Mr Cathal Hanely, Head of International at the <u>Competition and Consumer Protection Commission (CCPC)</u>, focused on "Post-pandemic Trades and Trends: AI and Beyond.



This panel featured presentations from <u>Dr Nicole Gross</u> of the National College of Ireland, <u>Professor Susi Geiger</u> of UCD Bussiness School and <u>Dr Qianlan Wu</u> of the University of Nottingham. Dr Lukasz Grzejdziak from the University of Strathclyde served as the discussant for this session.

Dr Gross and Professor Geiger's joint presentation, "Generative AI and the shaping of healthcare markets: A data justice perspective," critically examined the implications of generative AI in healthcare. Their talk highlighted six crucial tensions in the deployment of AI in healthcare, including the balance between improved science and potential biases, the concept of 'doctor on demand' versus automation and choicelessness, and the trade-offs between innovation and loss of public infrastructure.



They proposed the pathways forward, including endorsing responsible technology development, supporting and safeguarding citizens and society, and dynamically translating ethics into regulation.

Dr Qianlan Wu's presentation, "Has the global pandemic injected new meaning into unreasonable trade practices?" explored the impact of the COVID-19 pandemic on global trade practices, focusing on personal protective equipment (PPE) markets.



Dr Wu examined the interplay between trade policies, public health, and industrial strategies in personal protective equipment (PPE) manufacturing. She focused on the U.S. decision 2024 to significantly increase tariffs on PPE imported from China under Section 301 of the Trade Act 1974. Dr. Wu critically analysed the U.S. justification for this action, which cited China's allegedly unreasonable practices in technology transfer, intellectual property, and innovation. Using Bluesail Plc as a case study, she illustrated how Chinese government policies and fair competition review mechanisms shaped the PPE industry before and after the pandemic. Her presentation aimed to elucidate how notions of fairness have evolved post-pandemic.

<u>Dr Hab. Łukasz Grzejdziak</u> from the University of Strathclyde served as the discussant for the second panel and provided insightful commentary on the presentations, drawing on his expertise in EU competition law and state aid regulations.



Following the panel discussions, <u>Dr Mina Hosseini</u>, the Marie Skłodowska-Curie postdoctoral fellow at UCD Sutherland School of Law, who was also the workshop coorganiser, delivered closing remarks and introduced the Competition Conversation Network.



Dr Hosseini's closing address synthesised the key themes from the day's discussions, highlighting the interconnections between competition law, healthcare innovation, and market dynamics in the post-pandemic era. The introduction of the Competition Conversation Network underscores COMPHACRISIS's goal of establishing a platform for ongoing engagement and research in this critical area of law and policy.





UCD Sutherland School of Law

Healthcare at the Crossroads: COMPHACRISIS Workshop on Regulation, Innovation, and Market Dynamics

Friday 13 September 2024

UCD Sutherland School of Law

Harty Boardroom



AGENDA

9:00 AM – 9:30 AM Arrival and Registration

9:30 AM – 10:00 AM

Opening welcome and workshop overview: Professor Imelda Maher (UCD Sutherland School of Law)

10:00 AM - 11:15 AM: Panel 1: Competition in EU Healthcare Sector: Hospitals and Pharmaceutical Markets

Panel Chair 1: Professor Suzanne Kingston (UCD and the General Court of the European Union) (online)

Presentation 1: Dr Mary Guy (Liverpool John Moores University, UK): On The Quiet Power of National Decisions: Hospitals, State Aid, and Services of General Economic Interest

Presentation 2: Dr Diletta Danieli (University of Verona, Italy): *Regulatory exclusivities in the revised EU pharmaceutical legislation: revisiting the balance between innovation and competition*

Panel 1 Discussant: Dr Vincent Power (A & L Goodbody)

Q&A and Discussion (15 minutes)

11:15 AM - 11:45 AM: Coffee Break

11:45 AM – 1:00 PM: Panel 2: Post-pandemic Trades and Trends: AI and Beyond

Panel Chair 2: Mr Cathal Hanely (Head of International, The Competition and Consumer Protection Commission-CCPC)

Presentation 1: Dr Nicole Gross (NCI) and Professor Susi Geiger (UCD): Generative AI and the shaping of healthcare markets: A data justice perspective.

Presentation 2: Dr Qianlan Wu (University of Nottingham): Has the global pandemic injected new meaning into unreasonable trade practices?

Panel 2 Discussant: Dr Lukasz Grzejdziak (University of Strathclyde, UK)

Q&A and Discussion (15 minutes)

1:00 PM - 1:30 PM

Closing Remarks and Introduction of Competition Conversation Network: Dr Mina Hosseini (UCD Sutherland School of Law)

1:30 PM onwards

Networking Lunch downstairs in the Atrium

11:15 AM - 11:45 AM: Coffee Break

11:45 AM – 1:00 PM: Panel 2: Post-pandemic Trades and Trends: AI and Beyond

Panel Chair 2: Mr Cathal Hanely (Head of International, The Competition and Consumer Protection Commission-CCPC)

Presentation 1: Dr Nicole Gross (NCI) and Professor Susi Geiger (UCD): Generative AI and the shaping of healthcare markets: A data justice perspective.

Presentation 2: Dr Qianlan Wu (University of Nottingham): Has the global pandemic injected new meaning into unreasonable trade practices?

Panel 2 Discussant: Dr Lukasz Grzejdziak (University of Strathclyde, UK)

Q&A and Discussion (15 minutes)

1:00 PM - 1:30 PM

Closing Remarks and Introduction of Competition Conversation Network: Dr Mina Hosseini (UCD Sutherland School of Law)

1:30 PM onwards

Networking Lunch downstairs in the Atrium

SPEAKERS' INFORMATION:

Panel 1: Competition in EU Healthcare Sector: Hospitals and Pharmaceutical Markets

Panel Chair: Professor Suzanne Kingston (UCD and the General Court of the European Union) (online)

Professor Kingston is a Judge in the General Court of the European Union. She has lectured at UCD since 2007, and has published widely in the field of European law and governance, especially in the environmental, competition and economic, and human rights fields. Prior to her appointment as a judge, she was a Senior Counsel practising at the Irish bar and regularly appeared before the Irish and European courts. Professor Kingston is a graduate of Oxford University (BA in Law) and the University of Leiden, the Netherlands (LL.M. in European Community Law, PhD). She served as a référendaire (legal adviser) in the cabinet of Advocate General Geelhoed at the European Court of Justice, Luxembourg from 2004-2006. Prior to this, she practised EU law at the Brussels office of the US law firm, Cleary Gottlieb Steen & Hamilton (2002-2004) and was a stagiaire at the European Commission (DG Competition)(2001-2002). She has held a variety of visiting positions, most recently as international visiting professor of law and adjunct professor at Columbia Law School, New York. She has previously held visiting positions at Cambridge University, the University of Leiden, Queen's University, Belfast, and Osgoode Hall Law School, Toronto. In 2015, she was awarded a major research grant by the EU's European Research Council, investigating how the design of EU nature governance laws affects their effectiveness (http://effectivenaturelaws.ucd.ie). In 2017, she was honoured by Enterprise Ireland as one of Ireland's "Champions of EU Research", for achieving the highest-ranking Irish ERC grant across all disciplines in her category. She is Vice-President of the Irish Centre for European Law, and an editorial board member of the Irish Jurist.

Presentation 1: Dr Mary Guy (Liverpool John Moores University, UK): On The Quiet Power of National Decisions: Hospitals, State Aid, and Services of General Economic Interest

Dr Mary Guy is Senior Lecturer in EU and Public Law at Liverpool John Moores University, cocoordinator of the interdisciplinary EU Health Governance UACES Research Network, and UK National Contact Point for the European Association of Health Law. Her first monograph, Competition Policy in Healthcare - Frontiers in Insurance-Based and Taxation-Funded Systems (Intersentia 2019), examined competition reforms in Dutch and English healthcare. This has led to her being invited to present at the Dutch Council of State and advise the Belgian Competition Authority on hospital mergers. Her evidence has been cited by the Senedd Health and Social Care Committee regarding new legislation on procurement in the Welsh National Health Service. Dr Guy's latest work includes an article in the Journal of Health Politics, Policy and Law, "Solidarity as a political determinant of health: insights from EU competition policy", and her second monograph, "Solidarity in European Healthcare", is due to be published by Edward Elgar in 2026.

Presentation 2: Dr Diletta Danieli (University of Verona, Italy): *Regulatory exclusivities in the revised EU pharmaceutical legislation: revisiting the balance between innovation and competition*

Dr Diletta Danieli holds a PhD in European and International Legal Studies and is currently an Associate Professor of EU Law at the Department of Law of the University of Verona, where she teaches general and sectoral EU law subjects in both bachelor's and master's degree programs. She conducts research in various areas of EU law, including competition law with particular regard to the pharmaceutical sector. She has authored publications in her research fields and participated as a speaker at conferences and seminars.

Panel 1 Discussant: Dr Vincent Power (A & L Goodbody)

Dr Vincent Power is a Partner specialising in EU law, EU and Irish competition/antitrust law, merger control, regulatory law and transport law for national and international as well as public and private clients. He is Head of the A & L Goodbody's EU, Competition & Procurement Group, consistently ranked at the forefront of Irish law firms, and he is seen as the most experienced competition lawyer practising in Ireland. In 2019, he was elected Chairman of the European Maritime Law Organisation. Vincent has advised on most of the leading competition, merger control, EU law, cartel, abuse of dominance, State aid, joint venture, pricing, refusal to supply, competition investigations, Competition Authority / CCPC and competition litigation cases in Ireland over the last 30 years. He has been involved in several hundred merger filings in Ireland and the EU and has experience and expertise in all of the issues involved. He is the Chairman of the European Maritime Law Organisation. Vincent holds a BCL (National University of Ireland) as well as an LLM and PhD (University of Cambridge, where he was an Evan Lewis Thomas Law Student).

Panel 2: Post-pandemic Trades and Trends: AI and Beyond

Panel Chair: Mr Cathal Hanely (Head of International, The Competition and Consumer Protection Commission-CCPC)

Cathal Hanley is Head of International at the Irish Competition and Consumer Protection Commission ("the CCPC"). Prior to his current role in the CCPC, Cathal worked as senior economist in the CCPC's Competition Enforcement & Mergers Division where he led a number of antitrust investigations and merger assessments in the Irish financial services and energy markets. Cathal is a graduate of Trinity College Dublin, with a BBS degree in Business Studies and an MSc in Economics. He also holds a Postgraduate Diploma in EU Competition Law from King's College London. Prior to joining the CCPC Cathal worked as a portfolio manager with Bank of Ireland Asset Management and as a financial journalist with The Irish Times.

Presentation 1: Dr Nicole Gross (NCI) and Professor Susi Geiger (UCD): Generative AI and the shaping of healthcare markets: A data justice perspective.

Dr Nicole Gross is an Associate Professor at the National College of Ireland. Her research interests include market making and market shaping (especially in healthcare markets) but also practice-research, business models and market innovation. She is an active member of various research groups including the European Group for Organizational Studies, Misfires (<u>https://misfires.ucd.ie/</u>) and the Entrepreneurship-as-practice community. Nicole has been awarded funding from the Irish Research Council for some of her work under the New Foundations Scheme. Her research has been published in Organization Studies, Big Data & Society, Business & Society, Organization, Marketing Theory and the International Journal of Entrepreneurial Behaviour & Research, the Journal of Marketing Management and Ivey Cases (supplies Harvard Business Review). Nicole tweets under @tech_spaces.

Professor Susi Geiger is a Full Professor of Markets, Organizations and Society at University College Dublin, Ireland. Prof Geiger's expertise lies in the organization of markets, with a particular focus on pharmaceutical and data markets. Her current research focuses on issues of distributive justice and the collective good in these markets, for instance, in issues of assetisation, patenting, and access to medicines. She was recently appointed as a member of the WHO Technical Advisory Group in pharmaceutical pricing policies. She has just completed an ERC Consolidator Grant on market failures in pharmaceutical markets and held other prestigious grants in the past, including an EU Marie Sklodowska-Curie Global Fellowship in the area of digital health. Her work has been published widely in journals such as *Organization Studies, Research Policy, Journal of Management Studies, Big Data & Society, Social Science & Medicine, Economy & Society, Journal of Cultural Economy*, and many others. Her latest monograph entitled "Peak Pharma" will be published in early 2025 at Oxford University Press, and an edited volume entitled "Market Studies: Mapping, Theorizing and Impacting Market Action" is forthcoming in September 2024 at Cambridge University Press.

Presentation 2 : Dr Qianlan Wu (University of Nottingham, UK): *Has the global pandemic injected new meaning into unreasonable trade practices?*

Dr Qianlan Wu is an associate professor in the School of Law, University of Nottingham, and holder of the British Academy Innovation Fellowship for 2024-2025. Dr Wu researches international competition and trade laws, with an interest in critically assessing challenges raised by China to the international trade and competition law normative frameworks. Dr Wu holds a PhD in Law from the LSE and an LLM from the University of Edinburgh.

Panel 2 Discussant: Dr Lukasz Grzejdziak (University of Strathclyde, UK)

Dr Łukasz Grzejdziak is a Lecturer at the University of Strathclyde School of Law, an Associate Professor at the Department of European Economic Law, Faculty of Law and Administration, University of Łódź, Poland, and a Visiting Professor at the Sutherland School of Law of the University College Dublin. He is an academic collaborator of the Centre for Antitrust and Regulatory Studies, University of Warsaw. His areas of expertise are antitrust, state aid law, and economic regulation. He holds a Habilitation degree and a PhD in EU competition law. Łukasz Grzejdziak participated in numerous international scholarship programs, including the Ronan Harty Newman Fellowship at the University College Dublin Sutherland School of Law, the Senior Fulbright Award, Kosciuszko Foundation Grant (both at the IIT-Kent College of Law in Chicago) and the M. Bekker Program (at the Institute for Consumer Antitrust Studies, Loyola University Chicago). He worked as a researcher and a Member of the Centre for European Law, Vrije Universiteit Brussel, Belgium. He is an author of numerous publications within the area of Competition Law, including a triply prized monograph on State Aid for Services of General Economic Interest.

Hosts & Event Organisers: Dr Mina Hosseini and Professor Imelda Maher (UCD Sutherland School of Law)

Dr Mina Hosseini is a Marie Skłodowska–Curie postdoctoral fellow at UCD Sutherland School of Law. She received her PhD in Competition Law at Beheshti University in Tehran, Iran. Previously, she was a lecturer at the Tehran University of Science and Culture (USC), where she taught Contract Law, Competition Law, and Tort Law. She was also the academic editor and manager of the USC Journal of Modern Technologies Law. She has been a member of the Iranian Central Bar since 2008 and was a researcher at the Niroo Research Institute from 2014 to 2018, engaging in various projects about the electricity markets. In 2019, she was honoured with the National Student Book of the Year Award in the Law category for her monograph on Comparative Competition Law. Mina's research spans the interdisciplinary fields of competition law and policy, health law, and pharmaceutical law. Her current project, COMPHACRISIS, offers a comprehensive and in-depth inquiry into the enforcement of EU Competition law and policy in the pharmaceutical sector across normal, crisis, and post-crisis periods.

Professor Imelda Maher is the Sutherland Full Professor of European Law and Director of the UCD Dublin European Institute. She is also a former Dean of Law (Sept 2017-Sept 2021). She is interested in the relationship between law and governance and has published extensively on competition law and EU governance. Her recent work includes a monograph on treaty ratification in the EU (with Dermot Hodson), a series of articles on implementation of EU Law in Irish courts (with Rónán Riordan, Barry Rodger and Neža Šubic), and she is currently working on a monograph on international competition law (with Marek Martyniszyn). Elected a Member of the Royal Irish Academy in 2011, she is currently Senior Vice-President since 2023. Prof Maher is a member of the editorial advisory board of European Law Open, The European

Law Review and The Irish Yearbook of International Law and serves on the Advisory Board of the Cambridge Centre for European Legal Studies and of the Max Planck Institute for Innovation and Competition. She was elected an Honorary Bencher of Middle Temple London in 2019 and is a founding member of the European Law Institute, Vienna.

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