VIRTUAL EVENT

EU Pharmaceutical Law Forum

CELEBRATING 30 YEARS

17TH - 20TH MAY 2021 | 100% VIRTUAL

THE GO TO EU PHARMACEUTICAL LAW CONFERENCE FOR IN-HOUSE AND EXTERNAL LAWYERS ALIKE

Get to the Heart of Collaborations, Competition Law, Data Privacy, Patent Litigation, and Regulatory Frameworks.

AGENDA

WORKSHOP DAY
MONDAY 17TH MAY 2021
Think Tank: Sameness / Similarity for Orphan ATMP Products
Market Access for Innovative Therapies

MAIN CONFERENCE TRACKS		
TUESDAY 18TH MAY 2021	WEDNESDAY 19TH MAY 2021	THURSDAY 20TH MAY 2021
Competition Law & Patent Litigation	Regulatory Frameworks	Healthcare data, privacy and compliance
		Collaborations and Commercial Transactions

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The Virtual EU Pharmaceutical Law Forum Experience: What to Expect...

EU Pharmaceutical Law Forum's virtual experience has been tailored to you and your ease. Get up-to-speed with cutting edge topics and key trends delivered through multi-speaker formats, offering you differing views and in-depth analysis on the hottest topics affecting the industry from the comfort of your desk.

For speaking opportunities **contact leena.shaw@informa.com**
For sponsorship opportunities **contact linda.cole@informa.com**

YOUR DIGITAL EXPERIENCE

Expert insight delivered directly to your screen:
Get direct access to the information and experts who will help answer your burning questions. Enjoy the same high-level legal insights from the EU Commission, Competent Authorities, General Counsel and Private Practice law firms

Reshaping the networking experience:
Our virtual platform offers a sophisticated and fully interactive conference experience. Submit questions in advance or live to speakers during Q&As, live roundtables and panel discussions. Arrange one-to-one and group video meetings with speakers, sponsors and other delegates from around the world, and form connections with leading experts through our dedicated networking sessions

FLEXIBLE DIGITAL FORMAT - EASILY INTEGRATED WITH YOUR WORKING DAY

High level live-streamed content:
limited number of keynote speakers and high-level panels will be streamed live and timed to fit around your working day

More content-on-demand for learning at your convenience:
benefit from a packed roster of on-demand sessions pairing senior counsel with private practice, ensure a high-quality learning with practical industry perspective. And, with all presentations made available on-demand for 30-days post-event*, you will be able to attend more presentations than ever before!

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Live and on-demand content all count towards your CPD points

COMPETITION AND PATENT LITIGATION

	Live Programme & Available On-Demand	Accessible On-Demand Throughout to Watch At Your Leisure
9.30 – 10.10	**KEYNOTE INTERVIEW Update from EU Commission on Competition Law Enforcement** • Recent updates on competition law enforcement in the EU pharmaceutical sector and future focus for 2021 and beyond • Examining EU Commission response to COVID-19: comfort letters, exceptional framework guidance and the scope for more structural measures going forward **Paul Csiszár,** Director, DG Competition, European Commission To be joined by private practice	**DUAL DIALOGUE Antitrust Market Definition** • Practical guidance on how to define a "relevant" market and the redefinition of potential collaborators and competitors • Determining what is and isn't permissible • Understanding the thresholds and conditions for triggering block exemptions **Angela Staunton,** VP Antitrust, Bayer Pharmaceuticals To be joined by private practice
10.30 – 11.30	**INTERACTIVE DISCUSSION Excessive Pricing in the Pharmaceutical Industry** • Key updates and new developments on abuse of dominance through excessive pricing • Comparison of approaches and interpretations across different jurisdictions • Practical advice on pricing decisions and negotiations in current enforcement landscape **Alessandro Noce,** Head of the Agri-food, Pharmaceutical and Transportation Department, Italian Competition Authority (ICA) **Rainer Becker,** Head of Unit, DG Competition, European Commission **Jacob Westin,** Head of Legal, Nordics & EUCAN Competition Law Specialist, Takeda Pharmaceuticals **Lourenço Ventura,** Assistant Legal Director, Competition and Markets Authority (CMA) To be joined by private practice	**DUAL DIALOGUE Antitrust and IP Considerations for Mergers, Collaboration & Distribution** • Beyond just collaboration: M&A and full-function joint ventures; Distribution and Co-marketing; Innovation competition and acquisition of start-ups and biotech • Practical advice on structuring contracts to minimise risk **Chris Verleye,** Assistant General Counsel, Johnson & Johnson Law Department Europe To be joined by private practice
11.50-12.50	**INTERACTIVE DISCUSSION Anticompetitive Unilateral Conduct and Emerging Agreements** • Recent developments, updates and implications for the industry • Antitrust authority approach to market definition in the context of unilateral conduct • Examining the scope of activities, practices for delay and minimum value transfer to trigger antitrust action **Henri Piffaut,** Vice President, French Competition Authority, (subject to final confirmation) **Nicolas Pourbaix,** Legal Director, Amgen To be joined by private practice	**Examining Parallel Trade and Drugs Shortages** • New national developments and legislative initiatives to limit shortages and impact on parallel trade • How can drugs companies mitigate the risk of shortages? And their exposure to? • What is the impact of the Falsified Medicines Directive? • Jurisdiction of competition authorities **Nicolas Pourbaix,** Senior Counsel and Legal Director, Amgen
12.50 – 14.30	**ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME**	

14.30-15.00

KEYNOTE UPDATE European Commission Intellectual Property Action Plan

- Initiatives to ensure better enforcement and promote fair play globally for IP
- Implications for the pharmaceutical industry

Amaryllis Verhoeven, Head of the Intellectual Property Unit, DG Grow F3, **European Commission**

INTERACTIVE DISCUSSION Latest Trends in Preliminary Injunctions

- A multi-jurisdictional approach to latest developments and key trends
- Review of recent cases and enforcement decisions across UK, The Netherlands, France, Italy, and Switzerland
- Principles and trends; practical tips for (i) persuasive evidence (ii) cross-undertakings and (iii) balancing risks

15.20 – 16.20

INTERACTIVE DISCUSSION Latest Developments and Key Trends for Innovator vs. Innovator Collaborations and Disputes

- Appropriateness of injunctive relief in innovator vs. innovator disputes; compulsory licensing and potential crown use
- Principles of general application: what to patent, at what stage; what can you claim, what do you have support for?
- Validity and implication of patents that are too broad
- Review of recent cases and enforcement decisions

Shohta Ueno, Director, Dispute Resolution, **Regeneron Pharmaceutical Inc**

Nicolás Ruiz, Intellectual Property Head, **Esteve**

To be joined by private practice

Assessing the Current Status of SPCs

- New initiatives, latest developments and case law for SPCs: update on proposal for single SPC application and granting body
- Manufacturing waiver in practice and practical implementation
- Enforcement of SPCs: national court strategies
- SPC interaction with paediatric and orphan extensions

James Horgan, Assistant Managing Counsel, **Merck Sharp & Dohme Ltd**

REGULATORY FRAMEWORKS

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
10.00 – 10.40	**KEYNOTE PRESENTATION EU Commission Update on the Regulatory Landscape** • Updates on the EU Commission's pharmaceutical strategy • Areas of focus for legislative revision • Update on the review into pharmaceutical incentives and rewards **Florian Schmidt,** Deputy Head of Unit, DG SANTE, European Commission	**IP Regulatory Rights: New Developments in Orphan and Paediatric Medicines** • Review of the EU Paediatric and Orphan Medicines Regulations • Is the existing legislation fit for purpose and is there a need to change scope of qualifying conditions to increase protection for orphan medicines? **Georgia Gavriilidou,** Associate General Counsel, Amgen
11.00 – 12.00	**INTERACTIVE DISCUSSION Regulatory Flexibility: New Approaches and Future Scope** • Lessons learned from COVID-19 and how to convert these to "fit for innovation" regulation • New initiatives including rolling reviews and adapted approaches to regulatory assessments: could these initiatives be used more broadly? • Is current regulatory legislation sufficiently flexible to be responsive for future emergency situations? **Sandra Vanlievendael,** Head of Pharmaceutical Law, Legal Department, European Medicines Agency (subject to final confirmation) **Virginia Acha,** Associate Vice President, Global Regulatory Policy, MSD To be joined by private practice	**DUAL DIALOGUE Real World Evidence in Practice** • The rules governing the conduct of real world evidence projects: - The EU legislation - EMA draft guideline on registry-based studies - The FDA approach • Making real world evidence projects work in practice: - Planning, designing and implementing a successful project • Examples of real world evidence use in the context of regulatory approvals **Hilary Jones,** Senior Director, Legal, Gilead Sciences To be joined by private practice
12.00 – 14.00	**ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME**	
14.00 – 15.00	**INTERACTIVE DISCUSSION Pharmaceutical Market Access** • Increased synergy between HTA and regulatory agencies, and national and joint procurement levers being employed • Impact of international reference pricing from the US on European pricing and reimbursement landscape • Update on joint procurement alliances across Europe: legal challenges and points to consider for joint HTAs and joint negotiations **Francis Arickx,** Country Co-ordinator for Belgium, Beneluxa Initiative and Head, Directorate Reimbursement of Medicines and Pharmaceutical Policy, National Institute for Health and Disability Insurance (NIHDI RIZIV/INAMI) **Georgia Gavriilidou,** Associate General Counsel, Amgen To be joined by private practice	**DUAL DIALOGUE Pricing, IP and Regulatory Challenges for Companion Diagnostics and Combination Products** • Promotional, pricing and IP considerations for pharmaceuticals when combined with devices and companion diagnostics • MDR consequences for drug - device and device - drug combination products • IVDR consequences for companion diagnostics • Common pitfalls and challenges for software and digital tools **George Pickering,** Assistant General Counsel, Pharma R&D, Oncology and European Medical, GlaxoSmithKline To be joined by private practice

15.20 – 16.20

INTERACTIVE DISCUSSION Evolution of UK Medicines and Medical Devices Regulations

- Overview of new regulatory frameworks in the UK and support for life sciences innovation
- UK regulation in the national, European and Global contexts
- Practical challenges for industry in operating under the new regulatory systems across the UK

Victoria Kitcatt, Vice President and Assistant General Counsel, **Pfizer**

Steve Hoare, Quality, Regulatory Science & Safety Policy Director, **The Association of the British Pharmaceutical Industry (ABPI)**

Jonathan Mogford, Director of Policy, **MHRA**

To be joined by private practice

INTERACTIVE DISCUSSION Legal Considerations for Telehealth and Pharmaceutical Technology Associated Services to Support Patient

- Regulatory frameworks and IP implications for new technology
- Considerations for fair market value for new technology and innovation
- Ethical and legal risks: practical scenarios when thing go wrong and who is responsible

Rhianon Ebsworth, Senior Compliance Counsel, Business Ethics Compliance Office, **Novo Nordisk A/S**

Alejandro Bes, Global Senior Legal Counsel, Digital, **Novartis**

DUAL DIALOGUE Guidance for Digital Interactions: HPOs, HCPs, Patient Organisations and Patients

- Examining legal risks for digital interactions including e-communication, virtual events, e-commerce, e-advertising
- Guidance on marketing unauthorised products at HCP conferences
- Do regulators view digital interactions differently to face-to-face interactions?

Caroline Stockwell, VP, Head of Legal International, **Intercept Pharmaceuticals**

To be joined by private practice

HEALTHCARE DATA, PRIVACY & COMPLIANCE

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
10.00 – 11.00	**INTERACTIVE DISCUSSION New Legal Challenges for Managing Clinical Research Data** • Clinical research data, GDPR and COVID-19: challenges of bringing data in line with protocols and remote monitoring • Updates from European Data Protection Board (EDPB): new guidelines in context of pandemic • Processing of personal data in non- interventional studies and early access programmes • National adoption from individual country Data Protection boards • Challenges for multi-jurisdictional trials: focus on outliers including The Netherlands, UK and Germany • EMA's proposed Q&A regarding secondary use of clinical trial data **Veronique Ciminà,** Legal Officer, **European Data Protection Supervisor** **Maria Chiara Atzori,** Head, Group Data Privacy Policies, **Novartis International AG**	**On-going Tensions Surrounding GDPR and Data Sharing for the Pharmaceutical Industry** • Update on the key issues and tensions for healthcare data • Reviewing key regulations, guidance, policy and codes governing data sharing • Understanding and evaluating the different legal grounds and examining key questions
11.20 – 12.20	**INTERACTIVE DISCUSSION New Challenges for International Data Transfer** • EU Commission guidance for international data transfer following invalidation of Privacy Shield • Updates from USA, China, Russia and India on data localisation provisions and the impact on multi-jurisdictional trials • "Supplemental measures": where are we nearly a year after Schrems II? • Practical legal challenges and approaches **Chris Foreman,** Deputy Chief Privacy Officer, **Merck & Co., Inc.** **Martijn ten Bloemendal,** Global Legal Privacy Counsel, **AbbVie** **Ralf Sauer,** Deputy Head of Unit, DG Justice and Consumer International Data Protection Unit, **EU Commission** To be joined by private practice	**Trends in Whistleblowing, Anti-Bribery and Anti-Corruption Law and Enforcement** • EU antibribery, anticorruption and whistleblowing protection update • US FPCA code changes: update on the global impact of your operations • Best practice and benchmarking advice for implementing a successful compliance program
12.20 – 14.00	**ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME**	

COMMERCIAL TRANSACTIONS & COLLABORATIONS

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
14.00 – 15.00	**INTERACTIVE DISCUSSIONS: May the Force Majeure be with You and Contract Enforcement: Arbitration, Litigation or a 3rd Approach?** • COVID-19: a classic force majeure event? Lessons learnt from COVID-19 pandemic and contract enforcement challenges for the future • Examining benefits and challenges for different approaches for contract enforcement within the pharmaceutical sector: arbitration, litigation or a third way? **Niall O'Sullivan,** Legal Director, Licensing and Acquisitions, Established Pharmaceuticals, Abbott **Oliver Gandy,** Senior Legal Counsel, Boehringer Ingelheim **Adam McArthur,** Assistant General Counsel, Digital, IT and Operations, AstraZeneca To be joined by private practice	**Top 5 Clauses to Future Proof Contracts** • Lessons learnt from COVID-19 pandemic and contract enforcement challenges • Identifying the key clauses to ensure you are covered • Key points to consider in deal negotiations
		DUAL DIALOGUE Data Sharing in Collaborations and Commercial Transactions • Examining GDPR risks and strategies to share data in collaborations • How do you balance enhanced data subject rights with commercial incentives to share as much data as possible? • What is the minimum data needed to transfer products in sales transitions? • Can data be monetised as if it was IP? **Laetitia Szaller,** General Counsel and VP Business Development, AM Pharma
		Expert Tax Advice: Tax Regimes for Innovation and Considerations when Structuring Deals • Tax planning for collaboration and licencing agreements • Examining financial components of licencing agreements and their tax implications • Transfer pricing: intragroup and arm's length arrangements • Comparison of tax regimes for innovation across Europe To be led by private practice

End of conference

MARKET ACCESS FOR INNOVATIVE THERAPIES

10.00 - 12.00 **Application of Existing EU Frameworks**

- General principles
- EU co-operation on HTA/ legislative proposal/ EUnet HTA
- Joint procurements

Value and Pricing Discussion

- Comparison of different European national approaches to reimbursing and financing of innovative medicinal products (orphan, ATMP, novel therapies)
- Legal tools available to support value and pricing discussion

Innovative Payment Models and Structuring Contracts

- Agreements on net price with governmental authorities and other stakeholders
- Pay for Performance/payment for results/ risk sharing agreement
- Data collection/ real world evidence
- Transparency
- Discussion on the risk to pharmaceutical companies entering these agreements

Marieke Jansen - Head Legal Cell and Gene Europe, **Novartis**

THINK TANK: SAMENESS/SIMILARITY FOR ORPHAN ATMP PRODUCTS

14.00 - 16.00 **Regulatory Landscape for Assessment of Similarity for ATMPs**

- 2016 Commission consultation, 2018 amendment of Commission Regulation 847/2000 and high level ATMP Q&A
- General principles, precedents and global alignment
- How are the rules applied to the science in practice
- Challenges for health authorities in interpreting the guidelines

Data Requirements for Applications

- Difference between the New Active Substance (NAS)/Similarity assessment
- Importance of orphan exclusivity for ATMPs
- Data needed to prove (non)similarity for the purpose of assessing the scope of the orphan exclusivity
- Data needed to prove superiority for the purpose of derogating orphan exclusivity
- US FDA approach vs. EU approach and the relevance for global drug development

Practical guidance for Industry

- How have the regulations been applied to date?
- Where are the risks in the context of similarity for sponsors developing ATMPs for orphan indications?
- Industry concerns and additional guidance needed for the industry

Spyridon Drosos, Head of Litigation Office, Legal Department, **European Medicines Agency (EMA)**

Shaun Stapleton, VP Regulatory Affairs and Pharmacovigilance, **ReNeuron**

Constance Vercambre-Lallia, Head of Litigation Exclusivity, **Novartis**

Carla Schoonderbeek, Partner, **Hoyng Rokh Monegier**