informa connect

Monday 2nd - Friday 6th September 2024 Downing College, Cambridge, UK

24th Annual

European Pharma Law Academy

24 CPD Hours

DELVE INTO ALL ASPECTS OF EUROPEAN PHARMA LAW

This all-inclusive, 5-day residential conference enables professionals to gain an understanding of all the key aspects of European pharma law, as well as an update on the legal and policy changes affecting the industry.

The EU Pharma Law Academy will allow you to understand the legal issues affecting the pharma industry, and address them in a commercial and competent manner.

Gain insight into the long-standing conventions, the latest updates, and best practices from some of the leading experts in the pharma law field. The ideal event for those in a variety of job roles that are looking for detailed and intensive guidance on all the key aspects of pharma law.

The 2024 Academy is split into 5 days, each with its own theme:

Day 1: Fundamentals
Day 2: Advanced Regulatory Frameworks
Day 3: Advanced IP Law
Day 4: Advanced Cometition Law
Day 5: Compliance and MedTech

25
information packed presentations and workshops to build your pharma law knowledge

35
industry experts providing you with a wealth of knowledge

24
years advancing international professionals through an in-depth and immersive 5-day course

Email: legal.registrations@informaconnect.com
Web: https://informaconnect.com/european-pharma-law-academy/

informa connect

WHY ATTEND?

Get essential legal knowledge in just five days:

- Gain a comprehensive understanding of all aspects of European pharma law in theory and practice
- Attendees will develop expertise in the complexities of European law and development policies across the continent
- Gain practical knowledge through our hands-on workshops and interactive sessions

Who attends?

- Junior lawyers seeking to gain a specialism in European pharma law
- In-house counsel requiring a grounding in the core areas of European pharma law
- Experienced lawyers who need to know more about European pharma law
- Lawyers and professionals in government, public bodies and trade associations

Grow your professional network

Make lasting professional connections with our speakers and your fellow attendees.

Build upon your new relationships during informal and dedicated networking events throughout the day and during the evenings!

Immerse yourself in this residential experience and consolidate your learning by exchanging insights with your peers and speakers throughout the week.

Dive into historic Cambridge.

Relax and unwind at activities including:

- Barbeque & Quiz Night
- Punting on the River Cam
- Walking Tour of Historic Cambridge
- Gala Dinner

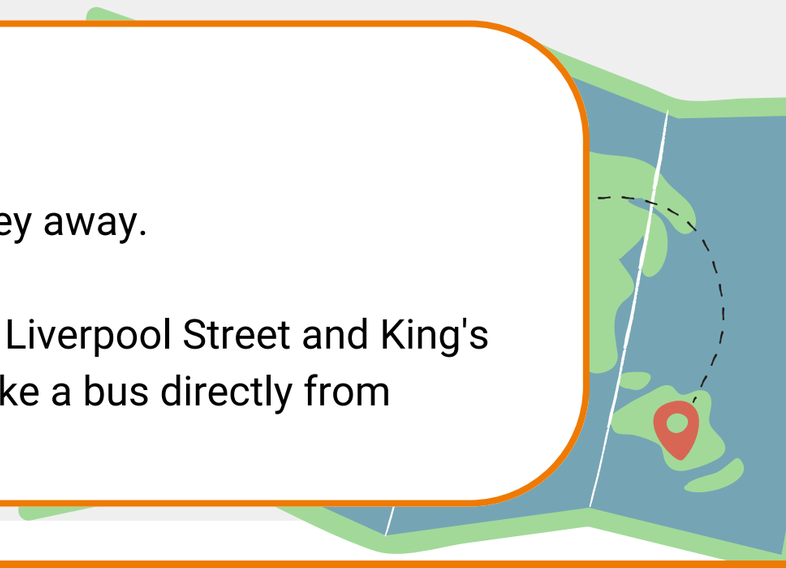
"Very detailed and comprehensive overview of the legal challenges that the pharmaceutical industry faces every day."
Group Legal Antitrust, Novartis

"The topics covered were excellent and for me they were the right balance of topics applicable to the pharma industry."
Senior Legal Counsel, Boehringer Ingelhelm

HOW TO GET THERE

The closest airport to Cambridge is Stansted Airport which is only a 30-minute bus or train journey away.

From London, the best way to get to Cambridge is by rail. Trains run every 15 minutes from both Liverpool Street and King's Cross stations. The journey takes from 45 to 90 minutes dependent on the train. You can also take a bus directly from Heathrow Airport to Cambridge, this takes 2 hours and 15 minutes.



Email: legal.registrations@informaconnect.com
Web: https://informaconnect.com/european-pharma-law-academy/

informa connect

35+ SPEAKERS

MEET & LEARN FROM THE PHARMA LAW EXPERTS AT THIS YEAR'S EVENT, INCLUDING:

Paul Csiszar
Director
DG Competition
European Commission

Sarah Faircliffe
Legal Director
Bird & Bird

Peter Bogaert
Partner
Covington & Burling

Livia Zamfiropol
Partner
DLA Piper

Cristiana Spontoni
Partner
Jones Day

Xisca Borrás
Partner
Bristows

WHO ATTENDS?

Past attendees have come from:

- Argentina
- Austria
- Belgium
- Chile
- Croatia
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Hungary
- Ireland
- Italy
- Japan
- Korea
- Lebanon
- Lithuania
- Macedonia
- Monaco
- Montenegro
- Netherlands
- Norway
- Poland
- Portugal
- Saudi Arabia
- Serbia
- Slovenia
- Spain
- Sweden
- Switzerland
- Taiwan
- Thailand
- Turkey
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States

And have worked in companies that include:

- A&L Goodbody
- Accord Healthcare
- Actelion Pharmaceuticals
- Allen & Overy
- Allergan
- Anthony Nolan
- Arthur Cox
- AstraZeneca
- Authority for Consumers & Markets
- Baker McKenzie
- Bayer
- Biogen
- Bird & Bird
- Boehringer Ingelheim
- Bristows
- Celgene
- Clinuvel
- CMS Cameron McKenna
- Covington & Burling
- Debiopharm
- DLA Piper
- Eisai
- Elan Drug Technologies
- EU Commission
- European Patent Office
- Eusa Pharma
- GlaxoSmithKline
- Glenmark Pharmaceuticals
- Hogan Lovells
- Hookipa Biotech
- Horizon Pharma
- Janssen Cilag
- Johnson & Johnson
- Latham & Watkins
- Leo Pharma
- Linklaters
- Matheson
- Merck Sharp & Dohme
- Mundipharma
- Novartis
- Novo Nordisk
- Pfizer
- PTC Therapeutics
- Public Health England
- Samsung Bioepis
- Saudi Food & Drug Authority
- Servier
- Setterwalls
- Shakespeare Martineau
- Shire
- SK Biotek Ireland
- Takeda
- Tesaro Bio
- Teva Pharmaceuticals
- Transgene

Email: legal.registrations@informaconnect.com
Web: https://informaconnect.com/european-pharma-law-academy/

informa connect

Day 1 - Monday 2 September 2024
Fundamentals

Registration & Morning Coffee
08:30 - 09:30

Chair's Opening Remarks
09:30 - 09:40

• Introductions from the delegates
• Objectives for the Law Academy

- Sarah Hanson, Co-head of the Life Sciences & Healthcare Sector Group, **CMS Cameron McKenna**

The EU Pharmaceutical Legal Framework
09:40 - 10:10

• EU legislation and process
• What is the role of the European Council, Commission and Parliament?
• European decision-making system: comitology
• What is the role of the Standing Committee?
• The EU Courts – preliminary rulings and dispute resolution
• What are the main EU pharmaceutical laws?
• What is the role of the European Medicines Agency and what is their relation to the national regulatory agencies?
• Potential consequences of Brexit in relation to EU pharmaceutical law

- Peter Bogaert, Partner, **Covington & Burling**

The Basics of IP Law for Pharmaceutical Innovations
10:10 - 10:40

• Overview of intellectual property (IP) rights and their importance in the pharmaceutical industry
• Understanding the patent system and its role in protecting pharmaceutical inventions
• Trademark protection for pharmaceutical brands and products
• Copyright protection for pharmaceutical works
• Trade secrets and their relevance to pharmaceutical research

- Dan Shaw, Partner, European and UK Patent Attorney, **J A Kemp**

Coffee Break
10:40 - 11:25

Clinical Trials: What You Need to Know
11:25 - 12:05

• What is a clinical trial?
• The type of clinical trial and what they are meant for
• What are the legal considerations?

- Cristiana Spontoni, Partner, Global Co-Leader of Health Care and Life Sciences, **Jones Day**

Orphan Drugs: Regulation and Incentives
12:05 - 12:50

• Orphan drugs designation
• IP benefits and exclusivity
• Recent case law

- Sarah Faircliffe, Legal Director, **Bird & Bird**

SPCs: The Basics
12:50 - 13:30

• Defining market authorisation
• Procedures within the EU

Lunch
13:30 - 14:30

The Fundamentals of Licensing Pharmaceutical Products
14:30 - 15:30

• Introduction to pharmaceutical licensing
• Types of pharmaceutical licensing agreements
• Key considerations in negotiating pharmaceutical licensing agreements
• Licensing agreements and regulatory requirements
• Licensing strategies and best practices

- Laetitia Szaller, General Counsel & Head of Compliance, **Egetis Therapeutics**
- Frances Stocks Allen, Partner, **Cooley**

Coffee Break
15:30 - 15:50

Early Access Schemes - Regulation and Scientific Reasoning
15:50 - 16:40

• The scientific logic behind early access schemes
• Regulatory approval schemes in Europe and USA
• Practical guidance for UK schemes
• PIM designation
• Scientific opinion
• EAMS public assessment report
• Accelerated access review – health technology assessment combined with benefit risk assessment

- Hein van den Bos, Partner, **Hogan Lovells International**

Day 1 - Monday 2 September 2024
Fundamentals

An Introduction to Competition Law in the Pharmaceutical Sector
16:40 - 17:20

• Overview of competition law and its relevance to the pharmaceutical industry
• Key principles of competition law applicable to the pharmaceutical sector
• Intellectual property rights and competition law
• Competition law challenges in the pharmaceutical industry
• Regulatory aspects and competition law in the pharmaceutical sector

- Peter Rowland, Of Counsel, **Herbert Smith Freehills**

Chair's Closing Remarks and Close of Day One
17:20 - 17:30

- Sarah Hanson, Co-head of the Life Sciences & Healthcare Sector Group, **CMS Cameron McKenna**

College Bar Opens
18:30

BBQ
19:30 - 20:30

Pub Quiz Night
20:30 - 22:00

Day 2 - Tuesday 3 September 2024

ADVANCED REGULATORY FRAMEWORKS

Breakfast in the Dining Hall
08:00 - 09:00

Chair's Opening Remarks
09:00 - 09:10

- Marie Manley, Partner and Head of the Life Sciences Practice, **Sidley**

Transparency in the EU Medicines Regime
09:10 - 09:55

• Reactive transparency
• Automatic transparency through EMA (proactive transparency policy and the Clinical Trials Regulation)
• Recent EU case law
• Navigating the use of personal data
• Comparison with other EU regimes

- Alison Dennis, Partner, **Taylor Wessing**

Paediatric Regulations
09:55 - 10:35

• Overview of pediatric regulations in the pharmaceutical industry
• Pediatric study planning and design
• Challenges and considerations in conducting pediatric trials
• Pediatric exclusivity and incentives
• Regulatory submissions and labeling requirements

- Chris Boyle, Senior Managing Associate, **Sidley Austin**

Strategic Alliances and Collaborations in the Pharmaceutical Sector
10:35 - 11:20

- Winsome Cheung, Partner, Covington & Burling
- Sarah Cowlishaw, Partner, Covington & Burling

Coffee Break
11:20 - 11:40

Regulatory Data Protection & Market Exclusivity
11:40 - 12:25

• A brief description of regulatory data protection (RDP)
• Principles of regulatory data protection
• Data Exclusivity and market exclusivity
  ◦ Differences in nature and enforcement of the right
• The concept of the global marketing authorisation
• New active substance and known active substance
  ◦ Legal, regulatory and scientific assessment
  ◦ Designation, legal consequences and enforcement
  ◦ Chemical and biological new active substance
• Update on relevant case law EU and national courts.

- Carla Schoonderbeek, Partner, **Arnold & Porter**

More Than a Decade of ATMP Regulation: Lessons Learned and Current Issues
12:25 - 13:30

• Overview of ATMPs and their regulatory landscape
• Lessons learned from the implementation of ATMP regulations
• Current regulatory issues and developments in the field of ATMPs
• Future prospects and challenges in ATMP regulation

- Marc Martens, Partner, Co-Head of the International Life Sciences and Healthcare Group, **Bird & Bird**

Lunch
13:10 - 14:10

Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals
14:10 - 15:10

- Regulations surrounding pharma advertising
- Online advertising

- Wendy Lloyd-Goodwin, Founder & General Counsel, **Life Science Law**

The EU Pharmaceutical Strategy: Changes ahead in the EU Regulatory System for Pharmaceuticals
15:10 - 15:40

• Overview of the Pharmaceutical Strategy: Understanding the objectives, goals, and scope of the strategy to enhance the pharmaceutical ecosystem in the EU.
• Legislative Revision: Delving into the proposed changes and updates to the EU regulatory system for pharmaceuticals and the reasons behind the need for such an overhaul.
• Implications for the Pharmaceutical Industry: Analyzing the potential effects of the proposed changes on pharmaceutical companies, healthcare providers, patients, and other stakeholders.
• Future Prospects: Anticipating the long-term impact of the regulatory reforms and potential challenges and opportunities for the pharmaceutical sector.

- Eveline Van Keymeulen, Partner, **Latham & Watkins**

Coffee Break
15:40 - 16:00

Day 2 - Tuesday 3 September 2024

ADVANCED REGULATORY FRAMEWORKS

Practical Workshop: Maximisation of IP Regulatory Rights

16:00 - 17:20

• Understanding the intersection of intellectual property (IP) and regulatory rights in the pharmaceutical industry
• Strategies for maximizing patent protection
• Leveraging regulatory exclusivities
• Coordinating IP and regulatory strategies

- Marie Manley, Partner and Head of the Life Sciences Practice, **Sidley**
- Chris Boyle, Senior Managing Associate, **Sidley Austin**

Chair's Closing Remarks and Close of Day Two

17:20 - 17:30

- Marie Manley, Partner and Head of the Life Sciences Practice, **Sidley**

Meet up at the Porter's Lodge for Guided Walking Tour of Cambridge

18:00 - 19:30

Dinner in the Dining Hall

19:30 - 20:30

Day 3 - Wednesday 4 September 2024

ADVANCED IP LAW

Breakfast in the Dining Hall
08:00 - 09:00

Chair's Opening Remarks
09:00 - 09:10

- Sally Shorthose, Partner, **Bird & Bird**

Cross-border IP Infringement
09:10 - 10:00

• Brussels I Regulation
• Unified Patent Court - the future of cross-border litigation?
• Cross-border injunctions
• Lessons for pharma lawyers

- Ruud Van Der Velden, Partner, **Hogan Lovells International**

Advanced SPCs
10:00 - 10:50

• Conditions for obtaining an SPC
• Latest status of the EU Commission roadmap for SPCs
• Examining the current shortcomings of the SPC regulation, including regular referrals to the Court of Justice
• Clarifying the current case law on SPC regulations
• How will Brexit impact SPCs?
• Paediatric extensions

- Marie Manley, Partner and Head of the Life Sciences Practice, **Sidley**

Coffee Break
10:50 - 11:10

Marketing Pharmaceuticals - Pricing & Reimbursement, Litigating Pricing & Patient Involvement
11:10 - 12:00

• Pricing and reimbursement considerations in pharmaceutical marketing
• Legal and regulatory aspects of pharmaceutical pricing
• Litigating pricing issues in the pharmaceutical industry
• Patient involvement in pharmaceutical pricing and access
• Market access and value-based pricing

- Hanneke Later-Nijland, Attorney-at-law, **Genome Lawyers**

Protecting Pharmaceutical Names – Trade Marks and Other Considerations
12:00 - 12:40

• Importance of protecting pharmaceutical names
• Trademark registration and protection for pharmaceutical names
• Trademark infringement and enforcement in the pharmaceutical sector
• Non-traditional trademarks in the pharmaceutical industry
• Other considerations for protecting pharmaceutical names

- Stephen Hodson, Partner, Patent and Trade Mark Attorney, **J A Kemp**

Lunch
12:40 - 13:40

Patent Portfolio Strategies for Pharma Inventions
13:40 - 14:20

• Importance of patent portfolio strategies in the pharmaceutical industry
• Developing a comprehensive patent portfolio strategy
• Patent prosecution and portfolio management
• Global patent portfolio considerations
• Patent portfolio monetization and commercialization

- Marc Wilkinson, Partner, **J A Kemp**

Unified Patent and the UPC
14:20 - 15:20

• Introduction to the Unified Patent and the UPC
• Implications of the Unified Patent and the UPC
• Future prospects and developments of the UPC

- Stephen Hodson, Partner, Patent and Trade Mark Attorney, **J A Kemp**

Coffee Break
15:20 - 15:40

Compounding by Pharmacists: Challenges for the (Bio)Pharmaceutical Industry
15:40 - 16:20

• In some Member States, compounding may currently be deployed as a way to curb the cost of medicines
• The compounding exemption and European rules regarding compounding
• The compounding exemption under patent law
• European case law
• What to do when you(r client) face(s) this challenge

- Hanneke Later-Nijland, Attorney-at-law, **Genome Lawyers**

Workshop: Product Licensing - Different Methods and Rationality to Maximise Profit
16:20 - 17:10

• Introduction to product licensing in the pharmaceutical industry
• Evaluating licensing opportunities
• Licensing models and strategies
• Negotiating licensing agreements

Day 3 - Wednesday 4 September 2024

ADVANCED IP LAW

• Maximizing profit through licensing

- Sally Shorthose, Partner, **Bird & Bird**

Chair's Closing Remarks and Close of Day Three
17:10 - 17:20

- Sally Shorthose, Partner, **Bird & Bird**

Meet-up at the Porter's Lodge for Punting on the Cambridge River
18:00 - 19:15

Dinner in the Dining Hall
19:15 - 20:15

Day 4 - Thursday 5 September 2024

ADVANCED COMPETITION LAW

Breakfast in the Dining Hall
08:00 - 09:00

Chair's Opening Remarks
09:00 - 09:10

- Gavin Robert, Senior Consultant, **Euclid Law**

Latest Developments and Cases in Competition Law in the Pharma Sector
09:10 - 09:50

- Paul Csiszar, Director at DG Competition, **European Commission**

Mergers and Acquisitions – Getting the Deal Through
09:50 - 10:30

• UK and EU merger control rules
• The search to catch "killer acquisitions" in the pharma sector
  ◦ Commission's new use of Article 22 referrals from Member States
  ◦ CMA's expansive approach to jurisdiction
• Potential competition and innovation theories of harm
• Reviewing the latest cases
• Future developments

- Gavin Robert, Senior Consultant, **Euclid Law**

Coffee Break
10:30 - 10:50

Discounts, Rebates and Bundling
11:00 - 11:45

• Overview of discounts, rebates, and bundling in the pharmaceutical sector
• Legal and regulatory considerations
• Strategic implications and benefits
• Financial and operational considerations
• Ethical considerations and stakeholder perspectives

- Peter Rowland, Of Counsel, **Herbert Smith Freehills**

Recent Developments in 'Disparagement' Cases – Key Takeaways for Pharma Companies
11:45 - 12:25

• What is 'disparagement' in competition law?
  ◦ The older precedents – Sanofi (Plavix) case, Schering Plough (Subutex) case
  ◦ The Janssen Durogesic (fentanyl) case
  ◦ The Novartis/Roche (Lucentis/Avastin) case
• Differences in approach when dealing with generics vs unauthorized medicinal products (off-label use)
• What limits to communication with healthcare professionals?
• How to handle interactions with health regulators?
  ◦ 'Legally unfounded interventions' vs freedom of speech
  ◦ Scientific arguments vs misleading information

- Liliana Eskenazi, Partner, Fréget **Glaser & Associés**

Lunch
12:25 - 13:25

Making Sure Your Agreements Comply with Competition Law
13:25 - 14:10

• The basics: when is an agreement likely to be caught?
• The horizontal and vertical block exemptions
• Supply agreements
  ◦ Incl. supply between generics and brand owners ("supply for delay"?)
• Licensing
• R&D collaboration agreements
• Information exchange

- Livia Zamfiropol, Partner, **DLA Piper**

Parallel Trade
14:10 - 15:00

• An introduction to parallel trade in the pharmaceutical industry
• The benefits and challenges of parallel trade
• Regulatory considerations and intellectual property implications
• Market dynamics and strategies in parallel trade
• Future trends and developments in parallel trade

Coffee Break
15:00 - 15:30

Key Considerations for Companies Under EU Commission Investigation
15:30 - 16:15

• Importance of understanding the investigative process for companies operating within the EU market
• Overview of Investigations:
  ◦ Explanation of the types of conduct and practices that may trigger an investigation by the European Commission (e.g., anti-competitive agreements, abuse of dominance).
  ◦ Discussion of recent trends and priorities in enforcement actions by the Commission
• Commission's investigative powers, including the gathering of evidence, requests for information, and site inspections
• Case studies highlighting notable investigations and their outcomes, with lessons learned for compliance and risk management

- James Killick, Partner, **White and Case**

Day 4 - Thursday 5 September 2024

ADVANCED COMPETITION LAW

Pay for Delay and Excessive Pricing
16:15 - 17:00

• Understanding pay for delay agreements
• Legal and regulatory considerations
• Impact of pay for delay on market competition
• Excessive pricing in the pharmaceutical sector
• Regulatory responses and enforcement actions

- Natalie Greenwood, Partner, **Euclid Law**
- Chris Verleye, Senior Legal Director, **Johnson & Johnson**

Chair's Closing Remarks and Close of Day Four
17:00 - 17:10

- Gavin Robert, Senior Consultant, **Euclid Law**

Drinks Reception
19:15 - 20:15

Gala Dinner
20:15 - 22:15

Day 5 - Friday 6 September 2024

COMPLIANCE IN MEDTECH

Breakfast in the Dining Hall
08:00 - 09:00

Chair's Opening Remarks
09:00 - 09:10

- Xisca Borrás, Partner, **Bristows**

Data Protection, Privacy and Making Use of Processed Data in Pharma
09:10 - 10:00

• Introduction to data protection and privacy in the pharmaceutical industry
• Compliance with data protection and privacy regulations
• Data utilization in the pharmaceutical industry
• Data anonymization and pseudonymization techniques
• Emerging trends and future considerations

- Kristof Van Quathem, Of Counsel, **Covington & Burling**

Digital Health: Digitalisation of Healthcare and Potential Pitfalls for Pharma Lawyers
10:00 - 10:50

• Regulatory landscape for digital health
• Legal considerations in digital health
• Compliance and risk management in digital health
• Emerging trends and future implications

- Vladimir Murovec, Counsel, **Osborne Clarke**

Coffee Break
10:50 - 11:20

Medical Devices: Overview and Current Legal Issues
11:20 - 12:05

• Introduction to data protection and privacy in the pharmaceutical industry
• Compliance with data protection and privacy regulations

- Annabelle Bruyndonckx, Partner, **Simmons & Simmons**

In Vitro Diagnostics
12:05 - 12:45

• Introduction to in vitro diagnostics
• Regulatory landscape for IVD devices
• Performance evaluation and clinical evidence for IVD devices
• Post-market surveillance and vigilance for IVD devices
• Emerging trends and challenges in IVD

- Xisca Borrás, Partner, **Bristows**

Lunch
12:45 - 13:45

Between Two Worlds: Addressing the Complexities of Combination Products and Companion Diagnostics
13:45 - 14:30

• Introduction to combination products and companion diagnostics
• Regulatory framework for combination products and companion diagnostics
• Development and manufacturing considerations
• Clinical evaluation and evidence generation
• Market access and post-market considerations

AI and Pharmaceutical Law
14:30 - 15:15

- Pieter Erasmus, Senior Associate, **Bird & Bird**

Coffee Break
15:15 - 15:45

Cybersecurity & Pharma: Patient Data, Public Perception & Preventing Attacks
15:45 - 16:45

- Charles-Albert Helleputte, Partner, Squire Patton Boggs

Chair's Closing Remarks and End of Academy
16:45 - 16:55

- Xisca Borrás, Partner, **Bristows**