

SESSIONS

DAY 1 - FUNDAMENTALS - 17/01/2022

European Pharma Law Academy

17-21 January 2022
Downing College
Cambridge University

Registration & Coffee

08:30 - 09:00
Main Agenda

Chair's Introduction to Pharmaceutical Law

09:00 - 09:10
Main Agenda

The EU Pharmaceutical Legal Framework

09:10 - 09:40
Main Agenda

- 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

Participants

Peter Bogaert - Partner, Covington & Burlington LLP

The Basics of IP Law for Pharmaceutical Innovations

09:40 - 10:10
Main Agenda

Participants

Vicki Allen - Partner, Patent Attorney, J A Kemp

Morning Coffee Break

10:10 - 10:30
Breaks

The Fundamentals of Marketing Authorisation

10:30 - 11:10
Main Agenda

Participants

Anneli Howard - Barrister, Monckton Chambers

Clinical Trials: What You Need to Know

11:10 - 11:50
Main Agenda

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

Participants

Cristiana Spontoni - Partner, JONES DAY®, Belgium

Orphan Drugs: Regulation and Incentives

11:50 - 12:35
Main Agenda

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

Participants

Sarah Faircliffe - Legal Director, Bird & Bird

SPCs: The Basics

12:35 - 13:15
Main Agenda

SPCs: The Basics

- Defining market authorisation
 - Procedures within the EU
-

Lunch

13:15 - 14:15
Breaks

The Fundamentals of Licensing Pharmaceutical Products

14:15 - 15:15
Main Agenda

Participants

Laetitia Szaller - General Counsel and Vice President of Business Development, AM-Pharma

An Introduction to Marketing Pharmaceuticals

15:15 - 15:45
Main Agenda

Participants

Robert Jenny - Senior Counsel and Director, AMGEN

An Introduction to Competition Law in the Pharmaceutical Sector

15:45 - 16:25
Main Agenda

Participants

Peter Rowland - Of Counsel, Herbert Smith Freehills

Chairperson's Closing Remarks and End of Day 1

16:25 - 16:35
Main Agenda

Participants

Alexander Meier - Partner, Preu Bohlig & Partner

Free time

16:35 - 17:15

Tour of Downing College

17:15 - 17:45
Networking Events

College Bar Opens

17:45 - 18:15
Networking Events

Dinner in Dining Hall

18:15 - 19:45
Networking Events

Pub Quiz

19:45 - 20:45
Networking Events

SCHEDULE

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10:00	10:10 - Morning Coffee Break	10:30 - The Fundamentals of Marketing Authorisation	
11:00		11:10 - Clinical Trials: What You Need to Know 11:50 - Orphan Drugs: Regulation and Incentives	
12:00		12:35 - SPCs: The Basics	
13:00	13:15 - Lunch		
14:00		14:15 - The Fundamentals of Licensing Pharmaceutical Products	
15:00		15:15 - An Introduction to Marketing Pharmaceuticals 15:45 - An Introduction to Competition Law in the Pharmaceutical Sector	
16:00	16:35 - Free time	16:25 - Chairperson's Closing Remarks and End of Day 1 16:35 - Free time	16:35 - Free time
17:00			17:15 - Tour of Downing College 17:45 - College Bar Opens
18:00			18:15 - Dinner in Dining Hall
19:00			19:45 - Pub Quiz

SESSIONS

DAY 2 - ADVANCED REGULATORY FRAMEWORKS - 18/01/2022

European Pharma Law Academy

17-21 January 2022
Downing College
Cambridge University

Chair's Opening Remarks

09:00 - 09:10
Main Agenda

Participants

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

Clinical Trials: Scope of the Regulation and Preparing for Implementation of the New Regime

09:10 - 09:55
Main Agenda

- What's so special about the EU clinical trials regulation (no 536/2014) and when does it come into force?
- How does this affect the business of a pharma company?
- The benefits & challenges of implementation
- BREXIT considerations
- Tips and tricks for pharma lawyers

Participants

Cristiana Spontoni - Partner, JONES DAY®, Belgium

Pediatric Regulations

09:55 - 10:35
Main Agenda

Participants

Genevieve Micheaux - Regulatory Life Sciences Partner, King & Spalding

Transparency in the EU Medicines Regime

10:35 - 11:10
Main Agenda

- 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.

Participants

Peter Bogaert - Partner, Covington & Burlington LLP

Regulatory Data Protection & Market Exclusivity

11:10 - 11:55
Main Agenda

- 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.

Participants

Carla Schoonderbeek - Partner, Hoyng Rokh Monegier

Lunch

11:55 - 12:55
Breaks

More than a decade of ATMP Regulation: lessons learned and current issues

12:55 - 13:40
Main Agenda

Participants

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

Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals

13:40 - 14:40
Main Agenda

- Regulations surrounding pharma advertising
- Online advertising

Participants

Robert Jenny - Senior Counsel and Director, AMGEN

Afternoon Networking & Refreshment Break

14:40 - 15:00

Practical Workshop: Maximisation of IP Regulatory Rights

15:00 - 16:20
Main Agenda

Participants

Chris Boyle - Associate, Life Sciences IP Regulatory, Sidley Austin LLP

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

Chairperson's Closing Remarks and End of Day 2

16:20 - 16:30
Main Agenda

Participants

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

Free time

16:30 - 17:40

Meet at Welcome Desk to Walk to River Cam

17:40 - 17:55
Networking Events

Punting on the River Cam

17:55 - 19:25
Networking Events

Pimms Drinks Reception and Barbecue (weather permitting) – College Bar Opens

19:25 - 20:25
Networking Events

SCHEDULE

DAY 2 - ADVANCED REGULATORY FRAMEWORKS - 18/01/2022

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10:00		10:35 - Transparency in the EU Medicines Regime	
11:00	11:55 - Lunch	11:10 - Regulatory Data Protection & Market Exclusivity	
12:00		12:55 - More than a decade of ATMP Regulation: lessons learned and current issues	
13:00		13:40 - Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals	
14:00	14:40 - Afternoon Networking & Refreshment Break	14:40 - Afternoon Networking & Refreshment Break	14:40 - Afternoon Networking & Refreshment Break
15:00		15:00 - Practical Workshop: Maximisation of IP Regulatory Rights	
16:00	16:30 - Free time	16:20 - Chairperson's Closing Remarks and End of Day 2 16:30 - Free time	16:30 - Free time
17:00			17:40 - Meet at Welcome Desk to Walk to River Cam 17:55 - Punting on the River Cam
18:00			
19:00			19:25 - Pimms Drinks Reception and Barbecue (weather permitting) – College Bar Opens

SESSIONS

DAY 3 - ADVANCED IP LAW - 19/01/2022

European Pharma Law Academy

17-21 January 2022
Downing College
Cambridge University

Chair's Opening Remarks

09:00 - 09:10
Main Agenda

Cross-border IP Infringement

09:10 - 10:00
Main Agenda

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

Advanced SPCs

10:00 - 10:50
Main Agenda

- 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
-

Participants

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

Morning Coffee Break & Networking

10:50 - 11:10
Breaks

Early Access Schemes - Regulation and Scientific Reasoning

11:10 - 12:00
Main Agenda

- 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
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Participants

Hein van den Bos - Partner, Hogan Lovells International LLP

Protecting Pharmaceutical Names – Trade Marks and Other Considerations

12:00 - 12:40
Main Agenda

Participants

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

Lunch

12:40 - 13:40
Breaks

Patent Portfolio Strategies for Pharma Inventions

13:40 - 14:20
Main Agenda

Participants

Amanda Simons - Partner, Patent Attorney, J A Kemp

Afternoon Coffee Break & Networking

14:20 - 14:40
Breaks

Compounding by Pharmacists: Challenges for the (Bio)Pharmaceutical Industry

14:40 - 15:20
Main Agenda

- 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
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Participants

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

Workshop: Product Licensing - Different Methods and Rationality to Maximise Profit

15:20 - 16:10
Main Agenda

Participants

Sally Shorthose - Partner, Bird & Bird

Chair's Closing Remarks

16:10 - 16:20
Main Agenda

Free time

16:20 - 18:45

Drinks Reception & Exhibition Viewing in Heong Gallery

18:45 - 19:30
Networking Events

Gala Dinner – Black-Tie/Formal Wear encouraged

19:30 - 21:00
Networking Events

College Bar Opens

21:00 - 22:00
Networking Events

SCHEDULE

DAY 3 - ADVANCED IP LAW - 19/01/2022

European Pharma Law Academy

17-21 January 2022
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TIME	BREAKS	MAIN AGENDA	NETWORKING EVENTS
09:00		09:00 - Chair's Opening Remarks 09:10 - Cross-border IP Infringement	
10:00	10:50 - Morning Coffee Break & Networking	10:00 - Advanced SPCs	
11:00		11:10 - Early Access Schemes - Regulation and Scientific Reasoning	
12:00	12:40 - Lunch	12:00 - Protecting Pharmaceutical Names – Trade Marks and Other Considerations	
13:00		13:40 - Patent Portfolio Strategies for Pharma Inventions	
14:00	14:20 - Afternoon Coffee Break & Networking	14:40 - Compounding by Pharmacists: Challenges for the (Bio)Pharmaceutical Industry	
15:00		15:20 - Workshop: Product Licensing - Different Methods and Rationality to Maximise Profit	
16:00	16:20 - Free time	16:10 - Chair's Closing Remarks 16:20 - Free time	16:20 - Free time
17:00			
18:00			18:45 - Drinks Reception & Exhibition Viewing in Heong Gallery
19:00			19:30 - Gala Dinner – Black-Tie/Formal Wear encouraged
20:00			
21:00			21:00 - College Bar Opens

SESSIONS

DAY 4 - ADVANCED COMPETITION LAW - 20/01/2022

European Pharma Law Academy

17-21 January 2022
Downing College
Cambridge University

Chair's Opening Remarks

09:00 - 09:10
Main Agenda

Participants

Gavin Robert - Senior Consultant, Euclid Law

Latest Development and Cases in Competition Law in the Pharma Sector

09:10 - 09:50
Main Agenda

Participants

Paul Csiszar - Director at DG Competition, European Commission

Making Sure Your Agreements Comply with Competition Law

09:50 - 10:35
Main Agenda

- 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

Participants

Livia Zamfiropol - Partner, DLA Piper

Morning Coffee Break & Networking

10:35 - 10:55
Breaks

Mergers and Acquisitions – Getting the Deal Through

10:55 - 11:35
Main Agenda

- 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

Participants

Gavin Robert - Senior Consultant, Euclid Law

Discounts, Rebates and Bundling

11:35 - 12:20
Main Agenda

Participants

Peter Rowland - Of Counsel, Herbert Smith Freehills

Lunch

12:20 - 13:20
Breaks

Workshop: Parallel Trade

13:20 - 14:50
Main Agenda

Participants

Melissa Healy - Associate, Skadden, Arps, Slate, Meagher & Flom LLP

Afternoon Coffee Break & Networking

14:50 - 15:20
Main Agenda

Strategic Alliances and Collaborations in the Wake of COVID-19

15:20 - 16:10
Main Agenda

Participants

David Hull - Partner, Van Bael & Bellis, Belgium

Michael Clancy - Partner, Van Bael & Bellis

Pricing & Reimbursement, Litigating Pricing & Patient Involvement

16:10 - 16:55
Main Agenda

Participants

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

Chair's Closing Remarks

16:55 - 17:05
Main Agenda

Free time

17:05 - 17:30

Walking Tour of Cambridge – Meet at Porters' Lodge

17:30 - 18:30
Networking Events

College Bar Opens

18:30 - 19:00
Networking Events

Dinner in Howard Building

19:00 - 20:30
Networking Events

SCHEDULE

DAY 4 - ADVANCED COMPETITION LAW - 20/01/2022

European Pharma Law Academy

17-21 January 2022
Downing College
Cambridge University

TIME	BREAKS	MAIN AGENDA	NETWORKING EVENTS
09:00		09:00 - Chair's Opening Remarks 09:10 - Latest Development and Cases in Competition Law in the Pharma Sector 09:50 - Making Sure Your Agreements Comply with Competition Law	
10:00	10:35 - Morning Coffee Break & Networking	10:55 - Mergers and Acquisitions – Getting the Deal Through	
11:00		11:35 - Discounts, Rebates and Bundling	
12:00	12:20 - Lunch		
13:00		13:20 - Workshop: Parallel Trade	
14:00		14:50 - Afternoon Coffee Break & Networking	
15:00		15:20 - Strategic Alliances and Collaborations in the Wake of COVID-19	
16:00		16:10 - Pricing & Reimbursement, Litigating Pricing & Patient Involvement 16:55 - Chair's Closing Remarks	
17:00	17:05 - Free time	17:05 - Free time	17:05 - Free time 17:30 - Walking Tour of Cambridge – Meet at Porters' Lodge
18:00			18:30 - College Bar Opens
19:00			19:00 - Dinner in Howard Building

SESSIONS

DAY 5 - BREXIT & BEYOND - LEGAL & REGULATORY COMPLIANCE ISSUES - 21/01/2022

European Pharma Law
Academy

17-21 January 2022
Downing College
Cambridge University

Chair's Opening Remarks

09:00 - 09:10

Data Protection, Privacy and Making Use of Processed Data in Pharma

09:10 - 10:00

Participants

Kristof Van Quathem - Of Counsel, Covington & Burling LLP

Beyond Brexit - Pharma's future regulatory outlook

10:00 - 10:45

Participants

Sally Shorthose - Partner, Bird & Bird

Sarah Faircliffe - Legal Director, Bird & Bird

Morning Coffee Break & Networking

10:45 - 11:00

Medical Devices: Overview and Current Legal Issues

11:00 - 11:45

Participants

Annabelle Bruyndonckx - Counsel, Simmons & Simmons LLP

Digital Health: Digitalisation of Healthcare and Potential Pitfalls for Pharma Lawyers

11:45 - 12:30

Participants

Vladimir Murovec - Supervising Associate, Simmons & Simmons

Lunch

12:30 - 13:30

Workshop: Cybersecurity & Pharma: Patient Data, Public Perception & Preventing Attacks

13:30 - 15:00

Participants

Charles-Albert Helleputte - Partner, Steptoe & Johnson

Diletta De Cicco - Associate, Steptoe & Johnson

Afternoon Coffee Break & Networking

15:00 - 15:20

The Future of Personalized Medicine: Regulatory challenges and opportunities

15:20 - 16:00

Participants

Eveline Van Keymeulen - Partner, Latham & Watkins

Pharmacovigilance & Risk Management

16:00 - 16:40

- Regulatory framework of phramacovigilance
 - Be inspection ready
 - - Preparation before an inspection
 - What the inspector expects
 - Common errors that lead to observations
 - How to respond to observations
 - - Planning and preparing an effective response to inspection observations
 - Coordinated response preparation
 - Assessment of underlying causes
 - Implementation of corrective and preventive action plans (CAPAs)
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Biologics, Biosimilars, Biobetters: Are They Special?

16:40 - 17:20

- Biologics, biosimilars, biobetters: what's in a name?
- Biosimilars and biobetters: regulatory framework (approval pathway, application dossier, new active substance criterion)
- Biosimilars: specific regulatory issues (naming, indication extrapolation, substitution)
- Biologics: SPC issues

Participants

Peter van Schijndel - Partner, Hoyng Rokh Monegier

Chairperson's Closing Remarks and End of Academy

17:20 - 17:35

SCHEDULE

DAY 5 - BREXIT & BEYOND - LEGAL & REGULATORY COMPLIANCE ISSUES - 21/
01/2022

European Pharma Law
Academy

17-21 January 2022
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12:00	12:30 - Lunch
13:00	13:30 - Workshop: Cybersecurity & Pharma: Patient Data, Public Perception & Preventing Attacks
14:00	
15:00	15:00 - Afternoon Coffee Break & Networking 15:20 - The Future of Personalized Medicine: Regulatory challenges and opportunities
16:00	16:00 - Pharmacovigilance & Risk Management 16:40 - Biologics, Biosimilars, Biobetters: Are They Special?
17:00	17:20 - Chairperson's Closing Remarks and End of Academy