

SESSIONS

PHARMA LAW ACADEMY 2023: DAY 1 - FUNDAMENTALS - 04/09/2023

European Pharma Law Academy

4th-8th September 2023

Downing College
Cambridge University

Registration & Coffee

08:30 - 09:30
Main Agenda

Chair's Welcome

09:30 - 09:40
Main Agenda

Participants

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

The EU Pharmaceutical Legal Framework

09:40 - 10:10
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 & Burling LLP

The Basics of IP Law for Pharmaceutical Innovations

10:10 - 10:40
Main Agenda

Participants

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

Morning Coffee Break

10:40 - 11:25
Breaks

Clinical Trials: What You Need to Know

11:25 - 12:05
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, Global Co-Leader of Health Care and Life Sciences, Jones Day

Orphan Drugs: Regulation and Incentives

12:05 - 12:50
Main Agenda

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

Participants

Sarah Faircliffe - Legal Director, Bird & Bird

SPCs: The Basics

12:50 - 13:30
Main Agenda

SPCs: The Basics

- Defining market authorisation
- Procedures within the EU

Participants

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

Lunch

13:30 - 14:30
Breaks

The Fundamentals of Licensing Pharmaceutical Products

14:30 - 15:30
Main Agenda

Participants

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

Frances Stocks Allen - Partner, Cooley

Afternoon Coffee Break

15:30 - 15:50
Main Agenda

Early Access Schemes - Regulation and Scientific Reasoning

15:50 - 16:40
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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An Introduction to Competition Law in the Pharmaceutical Sector

16:40 - 17:20
Main Agenda

Chairperson's Closing Remarks and End of Day 1

17:20 - 17:30
Main Agenda

Participants

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

College Bar Opens

18:30 - 19:30
Networking Events

BBQ

19:30 - 20:30
Networking Events

Pub Quiz

20:30 - 22:00
Networking Events

SCHEDULE

PHARMA LAW ACADEMY 2023: DAY 1 - FUNDAMENTALS - 04/09/2023

European Pharma Law Academy

4th-8th September 2023

Downing College
Cambridge University

TIME	MAIN AGENDA	BREAKS	NETWORKING EVENTS
08:00	08:30 - Registration & Coffee		
09:00	09:30 - Chair's Welcome 09:40 - The EU Pharmaceutical Legal Framework		
10:00	10:10 - The Basics of IP Law for Pharmaceutical Innovations	10:40 - Morning Coffee Break	
11:00	11:25 - Clinical Trials: What You Need to Know		
12:00	12:05 - Orphan Drugs: Regulation and Incentives 12:50 - SPCs: The Basics		
13:00		13:30 - Lunch	
14:00	14:30 - The Fundamentals of Licensing Pharmaceutical Products		
15:00	15:30 - Afternoon Coffee Break 15:50 - Early Access Schemes - Regulation and Scientific Reasoning		
16:00	16:40 - An Introduction to Competition Law in the Pharmaceutical Sector		
17:00	17:20 - Chairperson's Closing Remarks and End of Day 1		
18:00			18:30 - College Bar Opens
19:00			19:30 - BBQ
20:00			20:30 - Pub Quiz

Chair's Opening Remarks

09:00 - 09:10
Main Agenda

Participants

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

Transparency in the EU Medicines Regime

09:10 - 09:55
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

Katharina Ewert - Associate, Covington & Burling LLP

Pediatric Regulations

09:55 - 10:35
Main Agenda

Participants

Chris Boyle - Senior Managing Associate, Sidley Austin LLP

Morning Coffee Break and Networking

10:35 - 10:55
Main Agenda

Regulatory Data Protection & Market Exclusivity

10:55 - 11:40
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, Arnold & Porter

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

11:40 - 12:25
Main Agenda

Participants

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

Lunch

12:25 - 13:25
Breaks

Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals

13:25 - 14:25
Main Agenda

- Regulations surrounding pharma advertising
- Online advertising

Participants

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

Afternoon Networking & Refreshment Break

14:25 - 14:45

Practical Workshop: Maximisation of IP Regulatory Rights

14:45 - 16:05
Main Agenda

Participants

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

Chris Boyle - Senior Managing Associate, Sidley Austin LLP

Chairperson's Closing Remarks and End of Day 2

16:05 - 16:15
Main Agenda

Participants

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

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

17:30 - 19:00

Dinner

19:00 - 20:00
Networking Events

SCHEDULE

PHARMA LAW ACADEMY 2022: DAY 2 - ADVANCED REGULATORY FRAMEWORKS
- 05/09/2023

European Pharma Law
Academy

4th-8th September 2023
Downing College
Cambridge University

TIME	MAIN AGENDA	BREAKS	NETWORKING EVENTS
09:00	09:00 - Chair's Opening Remarks 09:10 - Transparency in the EU Medicines Regime 09:55 - Paediatric Regulations		
10:00	10:35 - Morning Coffee Break and Networking 10:55 - Regulatory Data Protection & Market Exclusivity		
11:00	11:40 - More than a decade of ATMP Regulation: lessons learned and current issues		
12:00		12:25 - Lunch	
13:00	13:25 - Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals		
14:00	14:45 - Practical Workshop: Maximisation of IP Regulatory Rights 14:25 - Afternoon Networking & Refreshment Break	14:25 - Afternoon Networking & Refreshment Break	14:25 - Afternoon Networking & Refreshment Break
16:00	16:05 - Chairperson's Closing Remarks and End of Day 2		
17:00	17:30 - Meet up at the Porter's Lodge for Guided Walking Tour of Cambridge	17:30 - Meet up at the Porter's Lodge for Guided Walking Tour of Cambridge	17:30 - Meet up at the Porter's Lodge for Guided Walking Tour of Cambridge
19:00			19:00 - Dinner

Chair's Opening Remarks

09:00 - 09:10
Main Agenda

Participants

Sally Shorthose - Partner, Bird & Bird

Cross-border IP Infringement

09:10 - 10:00
Main Agenda

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

Participants

Ruud van der Velden - Partner, Hogan Lovells International LLP

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

Marketing Pharmaceuticals - Pricing & Reimbursement, Litigating Pricing & Patient Involvement

11:10 - 12:00
Main Agenda

Participants

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

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

Vicki Allen - Partner, Patent Attorney, J A Kemp

Unified Patent and the UPC

14:20 - 15:20
Main Agenda

Participants

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

Afternoon Coffee Break & Networking

15:20 - 15:40
Breaks

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

15:40 - 16:20
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

Participants

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

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

16:20 - 17:10
Main Agenda

Participants

Sally Shorthose - Partner, Bird & Bird

Chair's Closing Remarks

17:10 - 17:20
Main Agenda

Participants

Sally Shorthose - Partner, Bird & Bird

Meet-up at the Porter's Lodge for Punting on the Cambridge River

18:00 - 19:15
Networking Events

Dinner

19:15 - 20:15
Networking Events

SCHEDULE

PHARMA LAW ACADEMY 2022: DAY 3 - ADVANCED IP LAW - 06/09/2023

European Pharma Law Academy

4th-8th September 2023

Downing College
Cambridge University

TIME	MAIN AGENDA	BREAKS	NETWORKING EVENTS
09:00	09:00 - Chair's Opening Remarks 09:10 - Cross-border IP Infringement		
10:00	10:00 - Advanced SPCs	10:50 - Morning Coffee Break & Networking	
11:00	11:10 - Marketing Pharmaceuticals - Pricing & Reimbursement, Litigating Pricing & Patient Involvement		
12:00	12:00 - Protecting Pharmaceutical Names – Trade Marks and Other Considerations	12:40 - Lunch	
13:00	13:40 - Patent Portfolio Strategies for Pharma Inventions		
14:00	14:20 - Unified Patent and the UPC		
15:00	15:40 - Compounding by Pharmacists: Challenges for the (Bio)Pharmaceutical Industry	15:20 - Afternoon Coffee Break & Networking	
16:00	16:20 - Workshop: Product Licensing - Different Methods and Rationality to Maximise Profit		
17:00	17:10 - Chair's Closing Remarks		
18:00			18:00 - Meet-up at the Porter's Lodge for Punting on the Cambridge River
19:00			19:15 - Dinner

SESSIONS

PHARMA LAW ACADEMY 2022: DAY 4 - ADVANCED COMPETITION LAW - 07/09/2023

European Pharma Law
Academy

4th-8th September 2023
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

Mergers and Acquisitions – Getting the Deal Through

09:50 - 10:30
Breaks

- 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

Morning Coffee Break & Networking

10:30 - 10:50
Breaks

Strategic Alliances and Collaborations in the Pharmaceutical Sector

10:50 - 11:35
Main Agenda

Participants

Megan McMellon - Associate, Allen & Overy

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

Afternoon Coffee Break & Networking

14:50 - 15:20
Main Agenda

Making Sure Your Agreements Comply with Competition Law

15:20 - 16:05
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 Zamfropol - Partner, DLA Piper

Pay for Delay and Excessive Pricing

16:05 - 16:50
Main Agenda

Chair's Closing Remarks

16:50 - 17:00
Main Agenda

Participants

Gavin Robert - Senior Consultant, Euclid Law

Drinks Reception

19:00 - 20:00
Networking Events

Gala Dinner – Black-Tie/Formal Wear encouraged

20:00 - 22:00
Networking Events

SCHEDULE

PHARMA LAW ACADEMY 2022: DAY 4 - ADVANCED COMPETITION LAW - 07/09/2023

European Pharma Law
Academy

4th-8th September 2023
Downing College
Cambridge University

TIME	MAIN AGENDA	BREAKS	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 - Mergers and Acquisitions – Getting the Deal Through	
10:00	10:50 - Strategic Alliances and Collaborations in the Pharmaceutical Sector	10:30 - Morning Coffee Break & Networking	
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 - Making Sure Your Agreements Comply with Competition Law		
16:00	16:05 - Pay for Delay and Excessive Pricing 16:50 - Chair's Closing Remarks		
19:00			19:00 - Drinks Reception
20:00			20:00 - Gala Dinner – Black-Tie/Formal Wear encouraged

SESSIONS

PHARMA LAW ACADEMY 2022: DAY 5 - COMPLIANCE AND MEDTECH - 08/09/2023

European Pharma Law
Academy

4th-8th September 2023
Downing College
Cambridge University

Chair's Opening Remarks

09:30 - 09:40

Participants

Xisca Borrás - Partner, Bristows

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

09:40 - 10:30

Participants

Kristof Van Quathem - Of Counsel, Covington & Burling LLP

Morning Coffee Break & Networking

10:30 - 11:00

Medical Devices: Overview and Current Legal Issues

11:00 - 11:45

Participants

Annabelle Bruyndonckx - Partner, Simmons & Simmons LLP

In Vitro Diagnostics

11:45 - 12:25

Participants

Xisca Borrás - Partner, Bristows

Lunch

12:25 - 13:45

Pharmacovigilance

13:45 - 14:05

Afternoon Coffee Break & Networking

14:05 - 14:35

Between Two Worlds: Addressing the Complexities of Combination Products and Companion Diagnostics

14:35 - 15:15

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

15:15 - 16:00

Participants

Vladimir Murovec - Managing Associate, Simmons & Simmons

Chairperson's Closing Remarks and End of Academy

16:00 - 16:15

Participants

Xisca Borrás - Partner, Bristows

SCHEDULE

PHARMA LAW ACADEMY 2022: DAY 5 - COMPLIANCE AND MEDTECH - 08/
09/2023

European Pharma Law
Academy

4th-8th September 2023
Downing College
Cambridge University

TIME	
09:00	09:30 - Chair's Opening Remarks 09:40 - Data Protection, Privacy and Making Use of Processed Data in Pharma
10:00	10:30 - Morning Coffee Break & Networking
11:00	11:00 - Medical Devices: Overview and Current Legal Issues 11:45 - In Vitro Diagnostics
12:00	12:25 - Lunch
13:00	13:45 - Pharmacovigilance
14:00	14:05 - Afternoon Coffee Break & Networking 14:35 - Between Two Worlds: Addressing the Complexities of Combination Products and Companion Diagnostics
15:00	15:15 - Digital Health: Digitalisation of Healthcare and Potential Pitfalls for Pharma Lawyers
16:00	16:00 - Chairperson's Closing Remarks and End of Academy