

# SESSIONS

DAY 1 - FUNDAMENTALS - 10/09/2018

European Pharma Law Academy

September 2019  
Downing College  
Cambridge, UK

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## Registration & Coffee

08:30 - 09:00  
Main Agenda

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## Chair's Introduction to Pharmaceutical Law

09:00 - 09:10  
Main Agenda

### Participants

**Alexander Meier** - Partner, Hoyng Rokh Monegier

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## 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

**Alexander Meier** - Partner, Hoyng Rokh Monegier

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## Summary of Key EUCJ Decisions

09:40 - 10:20  
Main Agenda

### Participants

**Genevieve Michaux** - Partner, Mayer Brown

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## Coffee Break

10:20 - 10:35  
Breaks

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## Clinical Trials: What You Need to Know

10:35 - 11:05  
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, Jones Day

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## The Basics of IP Law for Pharmaceutical Innovations

11:05 - 11:45  
Main Agenda

- Patent Filing and Defence
- Trademarks and Copyright

### Participants

**James Fish** - Partner, Trade Mark Attorney, J A Kemp

**Amanda Simons** - Partner, Patent Attorney, J A Kemp

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## An Introduction to Marketing Pharmaceuticals

11:45 - 12:15  
Main Agenda

### Participants

**Robert Jenny** - Senior Counsel and Director, AMGEN

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## Lunch

12:15 - 13:15  
Breaks

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## The Fundamentals of Marketing Authorisation

13:15 - 13:55  
Main Agenda

- Defining market authorisation
- Type of procedures within the EU
- Timelines of each procedure
- The pros and cons of the various procedures

### Participants

**Anneli Howard** - Barrister, Monckton Chambers

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## SPCs: The Basics

13:55 - 14:35  
Main Agenda

- Defining market authorisation
- Procedures within the EU

### Participants

**Charlotte Weekes** - Partner, Pinsent Masons

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## Getting to Grips with Market Access

14:35 - 15:15  
Main Agenda

- What are the features?
- What are the issues?
- Basics of pricing and reimbursement (i.e. NICE)
- Legal and ethical considerations

### Participants

**Paul Ranson** - Consultant, Morgan, Lewis & Bockius LLP, UK

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## Coffee Break

15:15 - 15:30  
Breaks

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## The Fundamentals of Licensing Pharmaceutical Products

15:30 - 16:10  
Main Agenda

- Maximising the commercial viability of a pharma patent
  - Pragmatic considerations from an in-house perspective

### Participants

**Laetitia Szaller** - Associate General Counsel, UCB

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## An Introduction to Competition Law in the Pharmaceutical Sector

16:10 - 16:55  
Main Agenda

- Why is Competition law so important?
  - Understanding of issues between undertakings (i.e. 101 TEU)
  - Understanding of the concept of dominance (i.e. 102 TEU)
- When is it a problem?
  - How to spot competition issues (e.g. the AZ case)
  - Strategies involving patents settlements

### Participants

**Matthieu Guerineau** - Head of Contracts and Legal Coordination Department, Servier, France

**Sandra Lazcano del Val** - Legal Counsel, Group Legal Antitrust Department, Novartis International AG

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## Orphan Drugs: Regulation and Incentives

16:55 - 17:45  
Main Agenda

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

### Participants

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

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## Chair's Closing Remarks and End of Day One

17:45 - 18:00  
Main Agenda

### Participants

**Alexander Meier** - Partner, Hoyng Rokh Monegier

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**Drinks Reception**

18:30 - 19:00  
Networking Events

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**Dinner**

19:00 - 20:00  
Networking Events

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**Pub Quiz**

20:00 - 21:00  
Networking Events

# SCHEDULE

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09:00		09:00 - Chair's Introduction to Pharmaceutical Law 09:10 - The EU Pharmaceutical Legal Framework 09:40 - Summary of Key EUCJ Decisions	
10:00	10:20 - Coffee Break	10:35 - Clinical Trials: What You Need to Know	
11:00		11:05 - The Basics of IP Law for Pharmaceutical Innovations 11:45 - An Introduction to Marketing Pharmaceuticals	
12:00	12:15 - Lunch		
13:00		13:15 - The Fundamentals of Marketing Authorisation 13:55 - SPCs: The Basics	
14:00		14:35 - Getting to Grips with Market Access	
15:00	15:15 - Coffee Break	15:30 - The Fundamentals of Licensing Pharmaceutical Products	
16:00		16:10 - An Introduction to Competition Law in the Pharmaceutical Sector 16:55 - Orphan Drugs: Regulation and Incentives	
17:00		17:45 - Chair's Closing Remarks and End of Day One	
18:00			18:30 - Drinks Reception
19:00			19:00 - Dinner
20:00			20:00 - Pub Quiz

# SESSIONS

DAY 2 - ADVANCED REGULATORY FRAMEWORKS - 11/09/2018

European Pharma Law Academy

September 2019  
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## Breakfast in the Dining Hall

08:00 - 09:00  
Networking Events

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## Chair's Opening Remarks

09:00 - 09:10  
Main Agenda

## Participants

**Robert Jenny** - Senior Counsel and Director, AMGEN

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

09:10 - 09:50  
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

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## Paediatric Regulations

09:50 - 10:40  
Main Agenda

- Reminder of scope of the EU Paediatric Regulation:
  - Obligations and rewards
  - Financial penalties
- Challenges and opportunities for industry:
  - Balance between obligations and rewards
  - Managing PIPs
- Major developments:
  - Case law
  - Commission Guideline
  - 10 year report to the Commission
  - Paediatric Extensions

## Participants

**Genevieve Michaux** - Partner, Mayer Brown

**Laurence Adegeest** - Senior Director Regulatory Affairs, EU Regulatory Disease Lead I/O & Lymphoma, Celgene International

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## Coffee Break

10:40 - 11:00  
Breaks

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## Data Protection, Privacy, and Freedom of Information

11:00 - 11:50  
Main Agenda

- How will GDPR and associated acts affect the pharma lawyer?
  - A global regulation
  - Patient consent
  - Penalties
- The importance of de-identification and anonymisation
- The right to be forgotten and what it means for pharma companies
- How to process a Freedom of Information request

## Participants

**Peter Bogaert** - Partner, Covington & Burlington LLP

**Kristof Van Quathem** - Special Counsel, Covington & Burling LLP

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## Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals

11:50 - 12:30  
Main Agenda

- Regulations surrounding pharma advertising
- Online advertising

## Participants

**Robert Jenny** - Senior Counsel and Director, AMGEN

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## Lunch

12:30 - 13:30  
Breaks

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## Pharmacovigilance & Risk Management

13:30 - 14:20  
Main Agenda

- Regulatory framework of pharmacovigilance
- 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)

## Participants

**Arianna Greco** - Vice President, Head of International Legal, Alnylam Pharmaceuticals

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## Regulatory Data Protection & Market Exclusivity

14:20 - 15:00  
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, Hoyngh Rokh Monegier

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## Biologics, Biosimilars, Biobetters: Are They Special?

15:00 - 15:40  
Main Agenda

- 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

**Eveline Van Keymeulen** - Counsel, Head of the Life Sciences Regulatory Practice, Allen & Overy

**Marjan Noor** - Partner, Allen & Overy

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## Coffee Break

15:40 - 15:55  
Breaks

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## Practical Workshop: Maximisation of IP Regulatory Rights

15:55 - 17:35  
Main Agenda

## Participants

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

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

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# SESSIONS

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## Chair's Closing Remarks and End of Day Two

17:35 - 17:45

Main Agenda

## Participants

**Robert Jenny** - Senior Counsel and Director, AMGEN

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## Meet at Welcome Desk to Walk to River Cam

17:45 - 18:00

Networking Events

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## Punting on the River Cam

18:00 - 19:30

Networking Events

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## Pimms Drinks Reception & Barbecue (Weather Permitting) - Cash Bar Opens

19:30 - 20:30

Networking Events

# SCHEDULE

DAY 2 - ADVANCED REGULATORY FRAMEWORKS - 11/09/2018

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09:00		09:00 - Chair's Opening Remarks 09:10 - Clinical Trials: Scope of the Regulation and Preparing for Implementation of the New Regime 09:50 - Paediatric Regulations	
10:00	10:40 - Coffee Break		
11:00		11:00 - Data Protection, Privacy, and Freedom of Information 11:50 - Marketing of Pharmaceutical Drugs & Interaction with Healthcare Professionals	
12:00	12:30 - Lunch		
13:00		13:30 - Pharmacovigilance & Risk Management	
14:00		14:20 - Regulatory Data Protection & Market Exclusivity	
15:00	15:40 - Coffee Break	15:00 - Biologics, Biosimilars, Biobetters: Are They Special? 15:55 - Practical Workshop: Maximisation of IP Regulatory Rights	
16:00			
17:00		17:35 - Chair's Closing Remarks and End of Day Two	17:45 - Meet at Welcome Desk to Walk to River Cam
18:00			18:00 - Punting on the River Cam
19:00			19:30 - Pimms Drinks Reception & Barbecue (Weather Permitting) - Cash Bar Opens

# SESSIONS

DAY 3 - ADVANCED IP LAW - 12/09/2018

European Pharma Law Academy

September 2019  
Downing College  
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## Breakfast in the Dining Hall

08:00 - 09:00  
Networking Events

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## Chair's Opening Remarks

09:00 - 09:10  
Main Agenda

## Participants

**Jerry Temko** - Former SVP & GC, Astellas Pharma Europe, UK

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## 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

## Participants

**Jürgen Dressel** - Former Head of Global IP Litigation Strategy, Novartis Pharma

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## 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

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## Coffee Break

10:50 - 11:10  
Breaks

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## 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

## Participants

**Dr Peter Feldschreiber** - Barrister and Physician, 4 New Square

**Koosje van Lessen Kloeke** - Partner, Leijnse Artz

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## Second Medical Use and Cross Label Infringement: An Ongoing Issue

12:00 - 12:40  
Main Agenda

- A brief history of the saga
- Examining the UK Supreme Court's changes in the law of UK patent infringement (Warner-Lambert v Actavis et al)
- The discovery of new uses for 'old' drugs
  - Sufficiency vs inventive step
- Steps legal teams need to take when confronted with suspected second medical use and cross label infringement

## Participants

**Lucy Barnes** - Partner, J A Kemp

**Amanda Simons** - Partner, Patent Attorney, J A Kemp

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## Lunch

12:40 - 13:40  
Breaks

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## Excessive Pricing: Recent Cases and Current Thought

13:40 - 14:30  
Main Agenda

- Excessive pricing legal test
- Abusive dominance through excessive pricing
- Decisions and developments including: Aspen, Pfizer, Flynn Pharma
- Examining approaches NCAs are taking

## Participants

**David Hull** - Partner, Van Bael & Bellis, Belgium

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## IPR and Competition Law in the Pharma Sector

14:30 - 15:20  
Main Agenda

- Licensing considerations
- Pricing - a potentially expensive issue
- Reverse patent settlement issues

## Participants

**Axel Schulz** - Partner, White & Case LLP

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## Coffee Break

15:20 - 15:40  
Breaks

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

15:40 - 17:20  
Main Agenda

## Participants

**Nikhil Patel** - Associate General Counsel - Global Commercial, DSM Sinochem Pharmaceuticals Netherlands B.V

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## Chair's Closing Remarks

17:20 - 17:30  
Main Agenda

## Participants

**Jerry Temko** - Former SVP & GC, Astellas Pharma Europe, UK

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## Drinks Reception

18:30 - 19:00  
Networking Events

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## Black-Tie Gala Dinner

19:00 - 20:00  
Networking Events

No jeans, t-shirts, or short-sleeved shirts.

Men: Suit/Tuxedo

Women: Suitable long dress.

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## Cash Bar Opens

20:00 - 21:30  
Networking Events

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# SCHEDULE

DAY 3 - ADVANCED IP LAW - 12/09/2018

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10:00	10:50 - Coffee Break	10:00 - Advanced SPCs	
11:00		11:10 - Early Access Schemes - Regulation and Scientific Reasoning	
12:00	12:40 - Lunch	12:00 - Second Medical Use and Cross Label Infringement: An Ongoing Issue	
13:00		13:40 - Excessive Pricing: Recent Cases and Current Thought	
14:00		14:30 - IPR and Competition Law in the Pharma Sector	
15:00	15:20 - Coffee Break	15:40 - Practical Workshop: Product Licensing - Different Methods and Rationality to Maximise Profit	
16:00			
17:00		17:20 - Chair's Closing Remarks	
18:00			18:30 - Drinks Reception
19:00			19:00 - Black-Tie Gala Dinner
20:00			20:00 - Cash Bar Opens



### Breakfast in the Dining Hall

08:00 - 09:00  
Networking Events

### 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 Csiszár** - Director, DG Competition, European Commission, Belgium

### More than a decade of ATMP's in Europe: legal and ethical issues of advanced therapies

09:50 - 10:30  
Main Agenda

- Social and ethical issues surrounding gene editing
- Legal status of CRISPR
- Future development and questions

### Participants

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

### Coffee Break

10:30 - 10:50  
Breaks

### Making sure your agreements comply with competition law

10:50 - 11:30  
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

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

### Mergers and Acquisitions – Getting the Deal Through

11:30 - 12:20  
Main Agenda

- EU regulations and recent publications on M&A
- Reviewing the latest cases
- EU Commission's innovation theory of harm
- Exploring the key issues and pitfalls
- Future developments

### Participants

**Alison Berridge** - Barrister, Monckton Chambers

### Lunch

12:20 - 13:20  
Breaks

### Effectively Dealing with Parallel Trade Issues

13:20 - 14:10  
Main Agenda

- Parallel imports in Europe – latest legal update
- Exhaustion of rights
- Modifying original packaging: what are the rules?
- Repackaging and re-labelling issues
- Impact of recent case law
- Impact of BREXIT

### Participants

**Marc Bauer** - Vice President - Head of Legal, Compliance and Corporate Affairs International, Tesaro

### Discounts, Rebates and Bundling

14:10 - 15:00  
Main Agenda

- An intro to discount and rebates
- When are discount and rebates an issue?
- How to reduce the threat

### Participants

**Marc Bauer** - Vice President - Head of Legal, Compliance and Corporate Affairs International, Tesaro

**Alice Wallace-Wright** - Senior Associate, Hogan Lovells

### Coffee Break

15:00 - 15:20  
Breaks

### eHealth: How Digital Health is Changing the World and Potential Pitfalls for Pharma Lawyers

15:20 - 16:10  
Main Agenda

- eHealth - healthcare of the future
- Current EU guidelines
- Potential liability issues
- Questions on jurisdiction

### Participants

**Claire Solk** - Senior Legal Counsel, AstraZeneca

**Warren Brown** - Senior Corporate Counsel, AstraZeneca

### Value Based Healthcare and Digital Marketing

16:10 - 16:50  
Main Agenda

### Participants

**Robert Jenny** - Senior Counsel and Director, AMGEN

### Digital Advertising of Pharma Products

16:50 - 17:30  
Main Agenda

- Social Media
- Programmatic ads
- Regulations, case law, and pitfalls

### Participants

**Ilja Morée** - Senior Director, Associate GC, Specialty Medicines Europe, Teva Pharmaceuticals Europe BV

### Chair's Closing Remarks & End of Pharma Law Academy

17:30 - 17:45  
Main Agenda

### Participants

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

# SCHEDULE

DAY 4 - ADVANCED COMPETITION LAW AND FUTURE LEGAL ISSUES - 13/09/2018

European Pharma Law  
Academy

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TIME	BREAKS	MAIN AGENDA	NETWORKING EVENTS
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10:00	10:30 - Coffee Break	10:50 - Making sure your agreements comply with competition law	
11:00		11:30 - Mergers and Acquisitions – Getting the Deal Through	
12:00	12:20 - Lunch		
13:00		13:20 - Effectively Dealing with Parallel Trade Issues	
14:00		14:10 - Discounts, Rebates and Bundling	
15:00	15:00 - Coffee Break	15:20 - eHealth: How Digital Health is Changing the World and Potential Pitfalls for Pharma Lawyers	
16:00		16:10 - Value Based Healthcare and Digital Marketing 16:50 - Digital Advertising of Pharma Products	
17:00		17:30 - Chair's Closing Remarks & End of Pharma Law Academy	