



## ANNUAL CONFERENCE ON EU LAW IN THE PHARMACEUTICAL SECTOR 2019

- Competition and intellectual property law
- Medical data and innovative technologies
- Access to medicines in the context of Brexit

Brussels, 21-22 February 2019

# UP GRADE

YOUR LEGAL  
EXPERTISE

**Pharmaceutical  
Law**



### Speakers

**Rainer Becker**, Head of Unit, DG COMP, European Commission, Brussels

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

**Martin Fitzgerald**, Deputy Director General, GIRP (European Healthcare Distribution Association), Brussels

**Edith Frénoy**, Director, Market Access/HTA, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels

**Leslie Galloway**, Chairman, EMIG (Ethical Medicines Industry group), London

**Emmanuelle Huck**, Programme/Policy Officer, DG CNECT, European Commission, Brussels

**Catherine Longeval**, Partner, Van Bael & Bellis, Brussels

**Lokke Moerel**, Professor, University of Tilburg, Senior Of Counsel, Morrison & Foerster, Berlin

**Ingo Müller**, Lawyer, Kohlpharma, Merzig

**Alexander Natz**, Secretary General, EUCOPE, Brussels

**Jörg Plessl**, Director, EU Affiliates, Regulatory Affairs, Norgine, Wettenberg

**Christian Tillmanns**, Partner, Meisterernst Rechtsanwälte, Munich

**Laura Whiting**, Counsel, Freshfields Bruckhaus Deringer, London

### Key topics

#### Competition law

Recent rulings from the CJEU and ongoing European Commission cases on pay for delay, off-label use and more

#### Patent law

SPC manufacturing waiver, specific mechanism for parallel imports

#### Data exclusivity

Revised EU definition of similar orphan designations, impact of recent General Court rulings on significant benefit

#### Emerging legal issues linked to new technologies and Digital Health

3-D printing and artificial intelligence, medical data, data sharing and "personalised medicines"

#### EU pharmaceutical law round-up

Recent developments on pricing and access to medicines, HTA post 2020, Brexit "preparedness"

Language  
English

Event number  
219R05

Organiser  
Florence Hartmann-Vareilles (ERA)



With the support of the Erasmus+ programme of the European Union

## Thursday, 21 February 2019

09:00 Arrival and registration of participants

09:15 **Opening of the conference**  
*Florence Hartmann-Vareilles*

### I. COMPETITION LAW IN THE PHARMACEUTICAL SECTOR

09:30 **Impact of recent rulings from the CJEU and update on Commission cases**

- Off-label use and by object restriction: *Hoffmann-la-Roche and Novartis*
- *Lundbeck* appeal on pay for delay (case of Citalopram)
- Pending cases before the European Commission

*Rainer Becker*

10:15 Discussion

### II. INTELLECTUAL PROPERTY LAW AND DATA EXCLUSIVITY

10:30 **Patents and Supplementary Protection Certificates (SPCs)**

- Proposal for an EU Regulation on SPC manufacturing waiver
- Combination: what is a product protected by a basic patent?
- Parallel imports and the specific mechanism in light of the CJEU ruling in *Orifarm*
- Progress on pharmaceutical incentives in the EU

*Laura Whiting and Ingo Müller*

11:30 Discussion

11:45 Coffee break

12:15 **Data exclusivity and orphan designations**

- Similar and biosimilar medicinal products: revised definition adopted by EU Regulation 2018/781
- Significant benefit: impact of recent judgments adopted by the General Court

*Peter Bogaert*

13:00 Discussion

13:15 Lunch

### III. DIGITAL HEALTH, EMERGING TECHNOLOGIES AND ACCESS TO MEDICAL DATA

14:30 **Ethical aspects linked to the collection, use and transfer of large amounts of medical data**

*Lokke Moerel*

15:00 Discussion

15:30 **Artificial intelligence, machine-learning and 3-D printing and the need for an EU legal framework**

- Progress and expectations of AI in the life-science sector
- Legal aspects linked to AI in the health sector
- Is the EU reform of the medical device legal framework already out of date?

*Christian Tillmanns*

16:30 Discussion

16:45 Coffee break

## Objective

This annual conference will bring legal practitioners working with the pharmaceutical sector up-to-date on the latest relevant regulatory developments, legislative initiatives and case law.

## Who should attend?

In-house counsel, lawyers in private practice, lawyers in national ministries and authorities dealing with regulation of the sector

## You will learn...

- What conclusions can be drawn from recent judgments of the CJEU on competition law in the pharmaceutical sector?
- When can a combination product be protected under patent law according to the CJEU's recent case law?
- How is the specific mechanism applied for parallel imports of medicines?
- What are the new EU rules for data exclusivity of orphan designations?
- What are the legal loopholes faced by the use of artificial intelligence in the life-science sector?
- What are the legal and ethical implications of sharing medical data in the EU?
- On which conditions can a Member State reimburse a medicinal product for indications not covered by an AMM?
- How to prepare for Brexit?

## What participants liked in 2018

...experienced speakers, topics are chosen well

...useful and practical information

...interesting discussions and great networking opportunities

## Your contact persons



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Assistant  
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17:15 **Access to digital data in the European Union: impact on the pharmaceutical and health sectors**

- EU initiatives on access and sharing of data
- Legal implications related to access and transfer of medical data
- Future data flows between the UK and the EU after Brexit

*Emmanuelle Huck*

17:45 Discussion

18:00 End of the first conference day

18:15 Reception

## Friday, 22 February 2019

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### IV. PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS FOR HUMAN USE

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09:00 **Off-label use: impact of the CJEU decision *Avastin /Lucentis***

*Catherine Longeval*

09:30 Discussion

09:45 **Access to medicines and reimbursement issues**

- Guidelines from the European Commission on shortage/ exports to Members States
- HTA: future approach post-2020
- Gene therapy and innovative payment models

*Edith Frénoy, Alexander Natz*

10:45 Discussion

11:00 Coffee break

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### V. IMPACT OF BREXIT ON THE HEALTH AND PHARMACEUTICAL SECTORS

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11:30 **Brexit “preparedness check”**

*Jörg Plessl, Martin Fitzgerald, Leslie Galloway*

12:30 Discussion

13:00 End of conference

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For programme updates: [www.era.int](http://www.era.int)  
 Programme may be subject to amendment.

## CPD

ERA's programmes meet the standard requirements for recognition as Continuing Professional Development (CPD). This event corresponds to **9 CPD hours**.

## Save the date

**The EU Trade Secrets Directive**  
 Brussels, 6 December 2018

**Three Months to Brexit – Where Do We Stand?**  
 Brussels, 6-7 December 2018

**Annual Conference on EU Trade Marks and Designs in Europe 2019**  
 Trier, 28-29 March 2019

**Annual Conference on European Data Protection Law 2019**  
 Brussels, 28-29 March 2019

**EU State Aid Proceedings and Litigation**  
 Brussels, 23-24 May 2019 2018

**Summer Course on European Intellectual Property Law**  
 Trier, 1-5 July 2019

## e-Presentations

**Recent Rulings of the General Court in EMA Access to Documents Cases**  
 Aleksandar Rusanov, March 2018

**Access to Documents in the EU in the field of Pharmaceutical Law – Recent CJEU Rulings**  
 Brian Kelly, March 2018

**Recent EU Developments on Patent Licence Agreements: Lessons Learned from the General Court's *Lundbeck* Ruling on Patent Settlement Agreements**  
 Ingrid Vandenborre, February 2017

**Recent EU Developments on Patent Licence Agreements: *Genentech v Hoescht* (C-567/14)**  
 Marleen H.J. van den Horst, February 2017

[www.era.int/elearning](http://www.era.int/elearning)

# Registration

## Annual Conference on EU Law in the Pharmaceutical Sector 2019

Brussels, 22-23 February 2019 / Event Number: 219R05



Europäische Rechtsakademie  
Academy of European Law  
Académie de Droit Européen  
Accademia di Diritto Europeo

### Registration

Fax: +49 (0) 651 93737-773

E-mail: [info@era.int](mailto:info@era.int)

Online registration:  
[www.era.int/?128326&en](http://www.era.int/?128326&en)

Postal address:  
ERA  
Postfach 1640  
D-54206 Trier

### Location

Rue de l'Aqueduc 118  
1050 Brussels  
Belgium

Language  
English

Contact Person  
Johanna Klaas  
Assistant  
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+49 651 9 37 37-223

### Hotel Recommendations

#### Four Points (Sheraton) Hotel

[www.fourpointsbrussels.com](http://www.fourpointsbrussels.com)  
[fourpoints.brussels@starwoodhotels.com](mailto:fourpoints.brussels@starwoodhotels.com)

#### Manos Stephanie Hotel

[www.manosstephanie.com](http://www.manosstephanie.com)  
[stay@manosstephanie.com](mailto:stay@manosstephanie.com)

#### Hotel Made in Louise

[www.madeinlouise.com](http://www.madeinlouise.com)  
[info@madeinlouise.com](mailto:info@madeinlouise.com)

Please contact the hotel directly to make your reservation.

### I would like to register for the ERA event mentioned above.

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### PLEASE USE BLOCK CAPITALS:

Title	<input type="checkbox"/> Ms	<input type="checkbox"/> Mr	Other	<input type="text"/>
First Name	<input type="text"/>			
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Organisation	<input type="text"/>			
Position	<input type="text"/>	Tel.	<input type="text"/>	
Department	<input type="text"/>			
E-Mail	<input type="text"/>			
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Postcode/City	<input type="text"/>	Country	<input type="text"/>	

**Evening programme:** I shall attend the function on Thursday, 21 February (at no extra charge).

### Registration fee

Fee	Standard	EU & ERA patrons*	Young lawyers & other groups**
Registration by 21/01/2019	€ 801.00 <input type="checkbox"/>	€ 480.60 <input type="checkbox"/>	€ 600.75 <input type="checkbox"/>
Registration after 21/01/2019	€ 890.00 <input type="checkbox"/>	€ 534.00 <input type="checkbox"/>	€ 667.50 <input type="checkbox"/>

#### \* EU and ERA Patrons

- Staff of European Union institutions and agencies;
- Staff of ERA's patrons: all EU Member States (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom), the German States, Scotland and the City of Trier
- Fellows of the European Law Institute

#### \*\* Young lawyers & other groups

- For young lawyers up to 30 years of age (important: the participant must provide a copy or details of his or her passport or identity card on registration);
- Full-time staff of universities or comparable academic institutions;
- Staff of charitable organisations or comparable institutions
- Registration of three or more employees from the same organisation

### Method of payment

- Credit card For registration with credit card payment please go to our website [www.era.int/?128326&en](http://www.era.int/?128326&en)
- Cheque Cheque number
- Bank transfer

I will transfer the registration fee to ERA's account at Deutsche Bundesbank Saarbrücken:  
IBAN: DE145900 00 00 00 58501900 – BIC: MARKDEF1590

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Place, Date

Signature