



## ANNUAL CONFERENCE ON EU LAW IN THE PHARMACEUTICAL SECTOR 2018

- Update on EU legislation and case law
- Incentives on innovation
- Access to data and data disclosure

Brussels, 1-2 March 2018

**UP  
GRADE**  
YOUR LEGAL  
EXPERTISE

**Pharmaceutical  
Law**



### Speakers

**Simone Boselli**, Public Affairs Director, EURORDIS, Brussels

**Alfonso Calles-Sanchez**, Legal and Policy Affairs Officer, Intellectual Property and Fight Against Counterfeiting, DG GROW, European Commission, Brussels

**Nicola Dagg**, Partner, Allen & Overy, London

**Marleen van den Horst**, Partner, BarentsKrans NV Advocaten, The Hague

**Brian Kelly**, Partner, Covington & Burling, London

**John Lisman**, Lisman Legal Life Sciences B.V., Heijen

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

**Geneviève Michaux**, Partner, Mayer Brown, Brussels

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

**Kristine Peers**, General Counsel, Legal Affairs, EFPIA, Brussels

**Rositsa Pencheva**, Case Handler, DG Competition, European Commission, Brussels

**Peter Picht**, Chair of Business and Commercial Law, Centre for Intellectual Property and Competition Law, University of Zurich

**Tapani Piha**, Head of Unit, Cross-Border Healthcare and eHealth, DG Health & Food Safety, European Commission, Brussels

**Aleksandar Rusanov**, Legal Administrator, European Medicines Agency, London

**Bart Van Vooren**, Associate, Covington & Burling, Brussels

### Key topics

#### Competition law in the pharmaceutical sector

- Mergers
- Alleged excessive pricing

#### Patent law in the pharmaceutical sector and other intellectual property incentives on innovation

- Recent CJEU rulings on supplementary protection certificates (SPCs)
- First results of the European Commission's public consultation on pharmaceutical incentives and the way forward

#### EU pharmaceutical law round-up

- Access to data and new digital initiatives on big data in public health
- Recent activities of the European Commission and the EMA
- Off-label use in Europe
- Advanced therapy medicinal products

Language  
English

Event number  
218R05

Organiser  
Florence Hartmann-Vareilles, ERA



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

# ANNUAL CONFERENCE ON EU LAW IN THE PHARMACEUTICAL SECTOR 2018

## Thursday, 1 March 2018

8:45 Arrival and registration of participants

9:15 **Opening of the seminar**  
*Florence Hartmann-Vareilles*

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### I. COMPETITION LAW IN THE PHARMACEUTICAL SECTOR

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Chair: *Florence Hartmann-Vareilles*

9:30 **Recent cases on mergers**  
*Rositsa Pencheva*

10:00 Discussion

10:15 **Alleged excessive pricing of pharmaceutical products**  
*Peter Picht*

10:45 Discussion

11:00 Coffee Break

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### II. ACCESS TO DATA IN THE HEALTH AND PHARMACEUTICAL SECTORS

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Chair:

11:30 **EU digital health care and big data in public health**  
*Tapani Piha*

12:00 Discussion

12:10 **Clinical trials data:**  
• **Implications of recent landmark rulings of the General Court**  
• **What to disclose and how?**  
*Aleksandar Rusanov and Brian Kelly*

13:00 Discussion

13:15 Lunch

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### III. INCENTIVES ON INNOVATION AND SUSTAINABLE ACCESS TO HUMAN MEDICINES

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14:30 **Patent extension in Europe: supplementary protection certificates, variations and second medical use**  
*Nicola Dagg*

15:15 Discussion

15:30 Coffee break

16:00 **Round table discussion: should the EU legal framework on incentives for innovation be revised?**

Chair: Alexander Natz

- Setting the scene
- Modifying Bolar and intellectual property exemption provisions during protection covered by a patent or SPC?
- Market exclusivity for orphan medicinal products: a need for better models?
- Pediatric regulation: what needs to be changed?

*Alfonso Calles-Sanchez, Kristine Peers, Simone Boselli, Nicola Dagg, Marleen van den Horst*

17:30 Discussion

18:00 End of first conference day

18:15 Networking reception

## Objective

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

## Who should attend?

In-house counsel and legal or patent advisers in pharmaceutical companies; lawyers in private practice dealing with pharmaceuticals and medical devices; lawyers in national ministries and authorities dealing with regulation of the sector

## You will learn...

- How are competition law cases before the Commission affecting the pharmaceutical sector?
- What can be learnt from the implementation of the EMA policy on the publication of clinical data?
- How can big data bring new challenges and opportunities for the health and pharmaceutical sectors?
- Should the EU legal framework on intellectual property incentives for innovation be changed?
- How is off-label use regulated in the European Union?
- How far are recent rulings of the CJEU and new EU proposals affecting the pharmaceutical sector?

## Venue

Management Centre Europe (MCE)  
Rue de l'Aqueduc 118  
1050 Brussels  
Belgium

## Your contact persons



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## Friday, 2 March 2018

### IV. EU PHARMACEUTICAL ROUND UP

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Chair: *Catherine Longeval*

09:15 **Preparing for Brexit in the life science sector**

*Bart Van Vooren*

09:45 Discussion

10:00 **Off-label use in the European Union: how is it regulated?**

*John Lisman*

10:30 Discussion

10:45 Coffee break

Chair: *Alexander Natz*

11:15 **Current liability issues in the life sciences sector**

*Catherine Longeval*

11:45 Discussion

12:00 **Legal challenges and hopes on advanced therapy human medicines**

*Geneviève Michaux*

12:30 Discussion

12:45 End of the conference

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

### What participants said in 2017

“... Perfect way to get updated with most relevant legal issues in pharma law...”

“...Even better than last year (that means very very good!)...”

“... Dynamic & up-to-date ...”

### Evening networking reception

On Thursday 1 March, you will have the chance to network with colleagues at our drinks reception.

### CPD

ERA's programmes meet the standard requirements for recognition as Continuing Professional Development (CPD). This event corresponds to **10 CPD hours**.

### Save the date

**Annual Conference on European Data Protection Law 2018**

Brussels, 16-17 April 2018

**Recent ECtHR and CJEU Case Law on Bioethics and Human Rights**

Strasbourg, 19-20 April 2018

**Annual Conference on European Social Security Law 2018**

Trier, 24-25 May 2018

**The Ownership, Use and Protection of Big Data in the Digital Single Market**

Brussels, 14-15 June 2018

**Summer Course on European Intellectual Property Law**

Trier, 25-29 June 2018

**Summer Course on European Competition Law**

Trier, 2-6 July 2018

**Annual Conference on European Patent Law 2018**

Brussels, 25-26 October 2018

### e-Presentations

**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

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