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

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

Speakers

Simone Boselli, Public Affairs Director, EURORDIS, Brussels

Alfonso Calles-Sánchez, 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 Longeaval, 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

With the support of the Erasmus+ programme of the European Union
Thursday, 1 March 2018

8:45  Arrival and registration of participants
9:15  Opening of the seminar
Florence Hartmann-Vareilles

I. COMPETITION LAW IN THE PHARMACEUTICAL SECTOR

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

II. ACCESS TO DATA IN THE HEALTH AND PHARMACEUTICAL SECTORS

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

III. INCENTIVES ON INNOVATION AND SUSTAINABLE ACCESS TO HUMAN MEDICINES

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

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Friday, 2 March 2018

IV. EU PHARMACEUTICAL ROUND UP

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

For programme updates: 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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