

Reform of the EU pharmaceutical legislation: Challenges and opportunities

11 December 2024 | Brussels, Belgium



09:00 – 09:30 Registration and Coffee

09:30 – 09:45 **Opening Address**
Dr. Christian Tillmanns – EPLA President

09:45 – 11:15 **Session I : New framework for regulatory data protection and market exclusivity**
This session will delve into the evolving landscape of regulatory data protection and market exclusivity in the EU, offering a comprehensive overview of the proposed reforms and their implications.

Regulatory data protection and market exclusivity under review
Peter Bogaert – Covington & Burling LLP, Belgium

New developments in patent law: SPCs, compulsory license and Bolar exemption | **Márk Kovács** – Schönherr Rechtsanwälte GmbH, Hungary

*Moderator: **Lluís Alcover** – Faus Moliner, Spain*

11:15 – 11:30 Coffee Break

11:30 – 12:30 **Session II : Shortage of medicinal products and supply security**
With the introduction of the new EU pharmaceutical legislation, this session will explore how these reforms aim to mitigate supply disruptions and enhance supply chain security.

Introduction of recent EU legislation and implications for stakeholders
Machteld Hiemstra – Simmons & Simmons, The Netherlands

The European Self-Care Industry Perspective on the Impact of Reformed Shortages Provisions | **Oliver Hartmann** – AESGP, Belgium

*Moderator: **Alessandro Spina** – European Commission*

12:30 – 13:30 Lunch Break

13:30 – 15:00 Session III: European Health Data Space (EHDS)

This session dives into the the legal framework and concept of the EHDS, including cross-border implications, and the EHDS's impact on industry.

EHDS and IP rights: Key implications for the pharmaceutical sector

Dr. Gabriela Maria Lenarczyk & Prof. Timo Minssen – University of Copenhagen, Denmark

Dealing with health data exchange in a cross-border third country/EU context | Oliver M. Brupbacher – Bär & Karrer, Switzerland

EHDS, Concerns and Opportunities: An Industry Perspective

Delphine Marchal – Eli Lilly and Company, Belgium

*Moderator: **Martin Draeby Gantzhorn** – Gorrissen Federspiel, Denmark*

15:00 – 15:30 Coffee Break

15:30 – 16:50 Session IV: Developments in advertising for medicinal products

This session will explore the latest developments, focusing on key trends, compliance challenges, and opportunities.

Overview of recent developments in pharmaceutical advertising

Vincenzo Salvatore – Simmons & Simmons, Italy

Insights on handling pre-authorization for OTC claims in France

Diane Bandon-Tourret – LexCase, France

*Moderator: **Andreas Natterer** – Schönherr Rechtsanwälte GmbH, Austria*

16:50 – 17:00 Closing Remarks

Dr. Christian Tillmanns – EPLA President

For more information about the speakers, and to engage with us, please visit our LinkedIn page:

 [European Pharmaceutical Law Association](#)

European Pharmaceutical Law Association (EPLA)

Avenue de Tervueren 13, B-1040 Brussels, Belgium – T: +32 2 736 53 54
secretariat@epla.eu • www.epla.eu
Transparency Register Number : 697023893816-22

