Big Data in the Pharmaceutical Sector
Between Protection and Transparency: Opportunities and Legal Challenges
27 February 2019 | Basel, Switzerland
Law Faculty, University of Basel
Peter Merian-Weg 8, 4052 Basel, Switzerland

Topics

• Keynote: Swiss Global Leadership in Personalized Health: Building a Swiss Personalised Health Network (SPHN)

• Transparency and Consent in the Era of Big Data

• Analysis and Personalized Medicine

• The CJEU Decision on CTD Transparency and Commercial Confidentiality

• Artificial Intelligence, Data Protection and Pharmaceutical Data

• Blockchain and Data Sharing in the Pharmaceutical Sector

• Regulatory Challenges and Opportunities in the Age of Big Data
Big Data in the Pharmaceutical Sector
Between Protection and Transparency: Opportunities and Legal Challenges

Data in the healthcare and pharmaceutical sector play an important role in various aspects. Data has already transformed many facets of the sector. Huge datasets are driving new drug discoveries and are making clinical trials more efficient. Wearable devices such as sleep trackers are creating more informed patients and the employment of more sophisticated data models has enabled healthcare professionals better to predict and prevent illness. From personalised medicine to AI assisted diagnostics and genetic engineering and sequencing, the possibilities, it seems, are endless.

However, despite its potential to improve patient care and the share price of pharmaceutical companies, legal and regulatory challenges remain. One need to look no further than the recent introduction of the General Data Protection Regulation (GDPR) to realise that significant regulatory challenges exits. With patients and regulatory becoming increasingly cognizant of data protection issues, regulatory restrictions are only going to increase.

This 1 day conference is specifically designed to help you navigate these challenges and recognise opportunities. Aimed at practitioners, regulators and academics alike, this event will help to avoid legal pitfalls and embrace opportunities as the healthcare sector enters into the era of big data.

Target Group

- In-house Legal Counsel
- Compliance and Data Protection Officer
- Regulatory Affairs Officer
- Researchers
- Life Science Attorneys
- Regulators
- Academics

For more information please check our website: www.lexxion.eu or contact Ms Melanie Usche: usche@lexxion.eu

EPLR – European Pharmaceutical Law Review

This journal identifies and analyses important legal and regulatory developments on the national, EU and international level. Furthermore, it provides an overview of and critically examines judgments that shape the interpretation and application of EU pharmaceutical law and policy, in particular those by the European Courts, international courts and tribunals such as the WTO’s Dispute Settlement Body, and higher national courts.

Topics covered by EPLR:

- Pharmaceutical law and policy in all jurisdictions
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- Medical devices
- Borderline cases: pharmaceuticals/food/cosmetics/chemicals
- Patents/trademarks
- Health technology assessment and pricing/reimbursement
- Digital health/big data

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Big Data in the Pharmaceutical Sector
27 February 2019 | Basel, Switzerland

8.30 – 9.00
Registration & Welcome Coffee

9.00 – 9.15
Welcome Notes

Morning Session

09.15 – 09.45
Keynote: Swiss Global Leadership in Personalized Health: Building a Swiss Personalised Health Network (SPHN)

Professor Dr. Torsten Schwede
Vice Rector Research of the University of Basel; Professor for Bioinformatics, Biozentrum, University of Basel; Chairman of the Scientific Expert Board of the Swiss Personalized Health Network SPHN; Director of the SPHN Data Coordination Centre; Group Leader at the Swiss Institute of Bioinformatics (SIB)

09.45 – 10.15
Transparency and Consent in the Era of Big Data Analysis and Personalized Medicine

Maria Chiara Atzori
Head of Data Privacy CH at Novartis International AG, Basel

10.15 – 10.45
Legal Considerations: Cell and Gene Therapies

Marieke Jansen
Head Legal C&G Europe, Novartis, Basel

10.45 – 11.15
Coffee Break

11.15 – 11.45
Big Data Applied to the Pharma Sector: Privacy vs. Transparency in the Light of the GDPR

Prof. Dr. Joaquin Cayon De Las Cuevas
University of Cantabria, Faculty of Law, Santander

11.45 – 12.15
Regulatory Challenges and Opportunities in the Age of Big Data

Nikolai Brun
Director of Division of the Medical Evaluation & Biostatistics Division (Danish Medicines Agency) and Chair of the HMA/EMA Joint Task Force on Big Data, Copenhagen

12.15 – 12.45
Discussion Round

12.45 – 14.00
Lunch Break & Networking

Afternoon Session

14.00 – 14.30
Artificial Intelligence, Data Protection and Pharmaceutical Data

Prof. Dr. Claudia Seitz, MA.
University of Basel, Faculty of Law, Center for Life Sciences Law (CLSL), Basel

14.30 – 15.00
CTD Transparency and Commercial Confidentiality according to the CJEU Case Law

Prof. Dr. Timo Minssen
University of Copenhagen, Faculty of Law, JUR Centre for Advanced studies in Bio-medical Innovation Law, Copenhagen

15.00 – 15.30
Coffee Break

15.30 – 16.00
Informational self-determination: Patient’s individual and global perspective

Philipp do Canto
Member of the Board and the Scientific Advisory Board of the Swiss Multiple Sclerosis Association (Schweizerische Multiple Sklerose Gesellschaft, SMSG)

16.00 – 16.30
Real World Data - Access, Lawful Use, Value, Control and Ownership

Florian Zabel
Chief Privacy Officer, Roche Group at F. Hoffmann-La Roche Ltd., Basel

16.30 – 17.15
Discussion Round and Panel Discussion
[Representatives from Academia, Pharmaceutical Companies, Authorities, Associations (Patients, Pharma etc.)]

17.15 – Closing & End of Conference
Registration is possible until 13 February 2019.
As the number of seats is limited, please register as soon as possible.

Venue
Law Faculty,
University of Basel
Peter Merian-Weg 8,
4052 Basel, Switzerland

CANCELLATION POLICY
Cancellations should be made in writing per post or fax. Please note that the full fee will be charged for cancellations received after 13 February 2019 (including illness or impediment which prevents him from fulfilling his duties). Nomination of a substitute remains possible. A cancellation arising by reason of too small a number of participants is effected no later than two weeks prior to the conference by the organisers. In this case the participation fee will be refunded. A requirement for reimbursement of travel and accommodation expenses as well as loss of working hours is not possible, unless such costs result from wantonly negligent or deliberate behaviour on the part of the organisers.

YES, I will take part in the conference

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Chemical Law Outside the EU and Chemical Law in Asia
20th and 21st February 2019 | Frankfurt on the Main, Germany

Lexxion Publisher kindly invites you to two seminars on chemical law and regulation. Our seminar on the 20th February will focus on developments in chemical regulations in important markets for the EU, including the USA, Canada, Brazil, Mexico, and the Eurasian Economic Union. Taking place on the following day, our second seminar will be concerned with recent changes to regulations in Asia.

A discount is available to anyone who would like to attend both seminars. The seminars will be held in german.

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