Editorial

In the months after the publication of the EPLR Issue 4/2018 at the end of last year, much has happened in pharmaceutical law and policy: With the adoption of Regulations 2019/5 and 2019/6 in January, the regulation of veterinary medicinal products has been taken out of Regulation 726/2004. This opportunity was also used to integrate some key elements of already existing rules on conditional marketing authorisations, variations and financial penalties into the Regulation. In February, the safety features – a unique identifier in the form of a barcode and an anti-tempering device – as introduced in the Falsified Medicines Directive became mandatory for most prescription and some over-the-counter medicinal products. Finally, the EMA has relocated to Amsterdam and is working from its temporary seat at the Spark building since Mid-March.

In February the summary report of the HMA-EMA Joint Big Data Taskforce (EMA/105321/2019) was published, providing recommendations and proposals for further action on big data derived evidence in the context of evaluation and monitoring of medicines. It provides a definition of big data and makes recommendations for 9 key challenges identified in this regard: standardisation, data quality, data sharing, data linkage, data analytics, regulatory acceptability of big data evidence, regulation of medical devices, expertise in the regulatory network and communication.

As the uses of Big Data and Artificial Intelligence in medicines in general and in the pharmaceutical sector specifically remain a hot topic, they also form the focus of our lead article ‘Artificial Intelligence as an Emerging Technology in the Pharmaceutical Industry: What are the Legal Challenges?’ by Christian Tillmanns and Markus Fuderer. The article provides an introduction to the uses of Artificial Intelligence in the pharmaceutical industry. They discuss AI in drug discovery and also in clinical trials, as well as the limitations the current legal framework imposes on the use of AI. In addition, the article raises the question of non-contractual liability for damages caused by the use of AI in the pharmaceutical industry, pointing to the absence of a common European legal framework, but examining the European Parliament Recommendation for Civil Law Rules on Robotics which assigns liability based on criteria such as the degree of training given by a person to the AI.

The reports section of this issue contains two reports from Denmark, as well as a report from the UK and Ukraine. Emil Kjeldahl Bjerregaard Bjerrum & Martin Dræbye Gantzhorn share their thoughts on the Danish Healthcare Reform Agreement, which includes the creation of the public authority Healthcare Denmark that will also incorporate the joint procurement service AMGROS and the Medicines Council. According to the authors, this reform will lead to increasingly centralised procurement and

might impact on the question if the recommendations of the Medicines Council could constitute administrative decisions.

Furthermore, Michael Christiani Havemann and Lise Aagaard present the Danish framework for subsidy and pricing of medicines for outpatient treatments, and after a detailed assessment of the Danish system call for joint EU medicine recommendations and common policies concerning pricing.

While the Brexit conundrum continues, Lorelei Ana Garagancea and Walter Fürst in their country report from the UK take a closer look at the implications of Brexit on clinical trials data exchange, taking into account the General Data Protection Regulation (GDPR) and the Clinical Trials Regulation (CTR). The relevance of the interaction between these two Regulations is also highlighted by the recent publication of Opinion 3/2019 of the European Data Protection Board on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR).

This issue also includes a report from Ukraine, which is not an EU Member State but with which the EU has concluded an Association Agreement. Borys Danevych and Anastasiia Filipiuk in their report present recent developments in the healthcare and life science sector such as the establishment of the National Agency for Medical Procurement, a new Reimbursement Programme and laws on Data Disclosure as well as Organ Transplantation. The report shows the far-reaching changes that the healthcare system that Ukraine is undergoing and how much these are shaped by EU influence.

Moreover, in a case note on the case C-423/17 *Staat der Nederlanden v WLC* (2019), Vicky Kriketou elaborates on the Courts interpretation of Articles 11(2) and 21(3) of Directive 2001/83/EC concerning carve outs. The Court was faced with a question concerning the effects on a marketing authorisation in case the deletion of indications or dosage forms from the summary of product characteristics is only requested after the marketing authorization has been granted.

Finally we are happy to provide a report of the first ever EPLR event which took place at the University of Basel on 27 February. Organised in cooperation with Prof. Dr. Claudia Seitz, the *Big Data in the Pharmaceutical Sector* event looked at the legal and regulatory challenges arising out of technological developments in this area.

As usual I would like to thank the Editorial team of the EPLR and our Editorial Board, as well as our authors and reviewers for their contributions to this issue, and end this editorial with a call to anyone who wants to share their insights with regard to European pharmaceutical law and policy to get in touch with us concerning the publication of an article, report or case note.

Sabrina Röttger-Wirtz
Managing Editor