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Editorial

Multiple factors indicate that big data, artificial intelligence and machine learning will play a crucial role in the evolution of pharmaceutical innovation.

The ongoing paradigm shift is fuelled by rapid technical advances that have greatly transformed and enhanced many facets of the pharmaceutical sector. Huge datasets are driving new drug discoveries and are making clinical trials more efficient, while sophisticated data models have enabled healthcare professionals to better predict and prevent illness using new technology ranging from precision medicine to AI assisted diagnostics as well as genetic engineering and sequencing. Big data and AI have also transformed international collaboration in the areas of drug discovery and development and in the future, the combination of pharmaceutical datasets with information technology based AI solutions will lead to new tools and improvements in pharmaceutical fields such as generative chemistry, image segmentation and analysis as well as optimization of cell and gene therapies.

However, despite all the advantages of fostering pharmaceutical innovation and improving patient care, this paradigm shift has brought significant legal challenges in various areas of the law, both on a national and international level.¹ While some of these technologies have not materialised yet and some areas are burdened with unrealistic hype and expectations, it cannot be denied that legal and regulatory challenges are already crystalizing. Some of the most important areas in which legal issues are becoming increasingly relevant include: '(1) the ethics of algorithmic decision-making, (2) the cybersecurity of AI systems, (3) the transparency and accountability of complex and opaque algorithmic decision making, (4) the protection of privacy, particularly with regard to the EU General Data Protection Regulation (GDPR), (5) questions concerning intellectual property rights, competition law and data ownership, (6) inequality, bias and discrimination resulting from AI applications, (7) quality assurance for both data and AI-driven decision-making, (8) the usability and interoperability of data, (9) liability, and (10) trust.'²

These core issues are often discussed in combination with calls to modernise national and international legislation, to improve public communication on AI matters, to enhance the knowledge and competencies of the workforce with regard to computational thinking, to adjust legal and regulatory procedures, as well as to reorganise crucial sectors such as healthcare.³

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- 1 Claudia Seitz, 'Big Data in the Pharmaceutical Sector: Current Developments and Legal Challenges' in Vermeulen and Lievens (eds), *Data Protection and Privacy under Pressure: Transatlantic Tensions, EU Surveillance and Big Data* (Maklu Uitgevers België 2017) 293-309.
- 2 Timo Minssen et al, 'AI, Big Data & Machine Learning (Denmark Chapter)' (*Global Legal Insights* 2019) 85.
- 3 *ibid.*

So there is much ado about something, and while the full impact of recent developments are not clear, it is obvious that the legal issues that we are - or will soon be - facing are elusive and complex. This already becomes apparent in the *Foreword* to this Special Issue where the Director of Division of the Medical Evaluation & Biostatistics at the Danish Medicines Agency and Chair of HMA-EMA Taskforce on Big Data, *Nikolai Brun*, starts out by reminding us of the enormous challenges that regulators and innovators are facing before the promise of these new technologies can be realised to their full potential.

Brun's Foreword is followed by a contribution from an interdisciplinary team of lawyers and computer scientists, including *Marcelo Corrales Compagnucci*, *Janos Meszaros*, *Timo Minssen*, *Arasaratnam Arasilango*, *Talal Ous* and *Muttukrishnan Rajarajan* who ask if 'Homomorphic Encryption' (HE) might be the 'Holy Grail' for big data analytics and legal compliance in the pharmaceutical and healthcare sector. The authors observe that HE provides a whole new layer of protection and at the same time allows the processing of data for secondary use and scientific research. But, they also point out that sufficient data utility cannot always be guaranteed. Hence, they note, that reconciling data protection under the GDPR with data utility will remain one of the greatest challenges in data and AI-driven pharmaceutical innovation.

The GDPR is also at the centre of the third contribution by *Annagrazia Altavilla*, *Jean Herveg*, *Viviana Giannuzzi*, *Annalisa Landi*, and *Adriana Ceci*, which examines the secondary use of paediatric data under the GDPR. The analysis emphasises the lack of specific provisions covering paediatric peculiarities under the GDPR, especially in the case of secondary use of data in international research projects. The authors therefore stress the need for further safeguards and tools for practice standardisation. Moreover, they highlight the importance of developing the governance of personal data processing for health research in order to reduce the risk of infringements of fundamental and children's rights.

What these and further privacy issues imply for medical practitioners is analysed by *Emmanuel Salami*, who explores AI, big data and the protection of personal data in medical practice. The author delivers an interesting examination of the various uses of AI in medical practice within the European Union/European Economic Area, with a special emphasis on potential privacy challenges that may arise therefrom.

Next *Ulrich M. Gassner* and *Ulrich Juknat* scrutinise regulatory approaches to AI in medical practice. In particular, the authors discuss the new EU guidelines on AI ethics, which provide more detailed information on how to cope with the future of governance of this technology. Furthermore, the contribution examines specific approaches of the U.S. Food and Drug Administration (FDA) with respect to AI uses in medical devices, which fundamentally differs from the EU guidelines.

Finally, *Núria Porxas* and *Carme Sanz*, address an increasingly important topic: AI health applications and related intellectual property challenges. The authors demon-

strate and argue that these challenges are particularly severe in the life sciences sector, which is much more used to patent protection of chemical and biological advances, rather than to the enormous speed of the AI evolution and its complex IP protection requirements. The authors propose that the solution to overcome them may be found in focusing more on simultaneous protection through a mixture of different categories of existing IP.

In light of such interesting papers, we are very excited about this special edition of the EPLR and believe that it will contribute to the necessary debates in this exciting and dynamic area of pharmaceutical law and regulation.

Timo Minssen and Claudia Seitz
Special Guest Editors