

Editorial

When we brought out the first issue of the European Pharmaceutical Law in late 2017, I as the Managing Editor had aimed to create a forum for the discussion of the latest pharmaceutical law and policy on EU as well as Member State level. Thanks to our amazing contributors and the excellent Editorial Board, I think I can proudly say that we achieved this in the last five years.

The past two years have been turbulent, especially in pharmaceutical law and policy. The EU is on the brink of a potentially profound reform of this regulatory area with the Commission's Pharmaceutical Strategy and the various initiatives that will spring from that. The pandemic and the consequential move towards a European Health Union already have led to a mandate extension of the European Medicines Agency. Moreover, in January 2022 the Clinical Trials Regulation finally entered into application. In these exciting times, it is therefore with mixed emotions – or as the German saying goes *mit einem lachenden und einem weinenden Auge* -, that I am announcing my decision to step down as Managing Editor of the journal that I helped to initiate and establish. This will be my last EPLR Editorial. However, I can certainly say with joy that we have found an excellent new Managing Editor, who will steer the journal through these exciting times: Jakob Wested. I want to use this opportunity to thank the team at Lexxion and especially the EPLR's Executive Editor Jakob McKernan for the fantastic collaboration over the years, and the Editorial Board for devoting their time and expertise to growing the journal from its creation in 2017 until today.

In this issue, our first article 'Are you AI's Favourite? EU Legal Implication of Biased AI Systems in Clinical Genetics and Genomics' by Anastasiya Kiseleva and Paul Quinn provide a nuanced analysis of the sources of bias in AI systems and how to categorize them taking into account three factors: 1) the level of granularity in classifications that are used; (2) the correlation of biases in AI systems with human biases; (3) the elements of an AI system that include biases. They then show the potential consequences of bias in AI systems: discrimination, stigmatization and inaccuracy, all of which are problematic especially in the context of genetics and genomics. The authors proceed to argue that the legal framework of protection against these consequences of bias require improvement and make several suggestions on how to regulate potential AI bias in the ongoing procedure for the EU AI Act proposal.

George Peretz and Xisca Borrás in their article 'A Case of Unforeseen Adverse Side-Effects?

The Ireland/Northern Ireland Protocol and Medicines Regulation' elaborate on the *status quo* of the impact of the Ireland/Northern Ireland Protocol to the Withdrawal Agreement between the United Kingdom and the European Union on medicines regulation in Northern Ireland. While the negotiations between the EU and the UK on the matter are still ongoing, the article examines the hurdles that have been created with

regard to the supply of medicines by keeping Northern Ireland part of the internal market with regard to the free movement of goods.

The first report in this issue by Mariana Ricardo discusses the Portuguese Law on the resilience of critical infrastructures, arguing that it falls short of recognizing and protecting the critical importance of the pharmaceutical and medical device industries. Karine Disdier-Mikus contributes a detailed report on the French measures against counterfeiting in the pharmaceutical sector.

I would like to close this Editorial by thanking you readers for your interest, and those readers that became contributors for helping to make the EPLR the valuable contribution to the EU pharmaceutical law and policy debate that it has become. I wish Jakob Wested, the team at Lexxion and the Editorial Board all the best for the future of the EPLR. I am certain that many exciting issues are awaiting us, and I look forward to reading them and watching the journal and its community grow even further.

Sabrina Röttger-Wirtz
Managing Editor