Foreword

In this issue of the European Pharmaceutical Law Review the exciting but also challenging areas of artificial intelligence (AI), machine learning and big data are discussed. It is an area which continues to develop at an unprecedented pace, and forces everyone to think in novel ways to address challenges in areas of drug development, approval and post-marketing surveillance.

Industry innovators, as well as regulators, prescribing physicians and patients all have to face this new reality, and all need to be informed about the opportunities this new technology affords, but also look at it critically by employing rigorous scrutiny to ensure it adds value, and not just confusion.

As drug and device development increasingly converge, the previously separated areas of regulation also need a harmonised approach from legislators and regulators going forward. One simply cannot look at one area in isolation. In addition, it is important to ensure that patients have continued access to efficacious and safe therapies that are evaluated and monitored throughout their lifecycle in a coherent way.

The European Medicines Agency and the Heads of Medicines Agency in Europe set up a joint task force on Big Data two years ago. As stated recently in the report¹ from the Joint HMA/EMA Task Force: 'AI, defined as a self-learning evolution of well-known adaptive statistics, is already part of the regulatory landscape.'

Machine learning algorithms where the algorithm incorporates feedback for continuously optimised output have already been incorporated in randomisation algorithms, and many devices use these techniques. Further development of AI into Natural Language Processing recognising and processing free text, recognising images, robotics guiding surgical instruments, and even Deep Learning Algorithms are now part of the data handling landscape regulators have to assess.

Several considerations become apparent when one considers the constantly evolving nature of AI. Firstly, no algorithm will ever perform any better than the data sets it is trained on. Thus, the output will reflect the distribution and variability of data in the training data set.

It is clear that regulators cannot, and should not accept the so-called 'black box' concept, in which algorithms simply perform in a vacuum without any checks and balances. It is therefore imperative that regulators require algorithms to 'explain themselves' ie to be programmed in advance with a view towards being interrogated. AI-

gorithmic code should be more transparent, and available for review by regulators. Outcomes of, and changes to, algorithm use (safety and efficacy), need to be subject to post-marketing surveillance mechanisms, just like it is done today when monitoring drug safety after marketing authorisation. Another option is to actively try to falsify a primary algorithm using a secondary ‘attack’ algorithm and only when this fails accept the primary algorithm as ‘true’.

There is no doubt that the use of advanced analytical tools and AI have the potential to greatly improve the development, manufacturing, post approval surveillance and personalisation of medicines, as well as the data handling and even accuracy and predictability in health care. These methods must however be held accountable to regulatory standards. Only then can the true potential of these technologies be safely deployed.

Lastly, ethical and legal issues surrounding data ownership, access, sharing and transfer across organisations and borders need to be discussed, and ways to safely use health data without compromising patient privacy need to be developed. Patients rightly expect their data to be used for the benefit of themselves and future patients, and this requires data to be treated with respect and integrity. At the same time, it is important not to prohibit innovation. Striking a delicate balance between the needs of industry, researchers, innovators, patients and physicians will prove to be a challenge. While data needs to be shared, it must be done in a secure way. But that applies to all the stakeholders. Simply expecting patients to share their data without industry being willing to do the same rings false and a ‘two-way street framework’ for the benefit of all future patients needs to be developed. Only then can the promise of these new technologies be realised to their full potential.

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