Digitization, algorithmization, and artificial intelligence in pharmaceutical law¹

Pharmaceutical law is not immune to the digitization megatrend. Regulation (EU) No 536/2014 of 16 April 2014 governing clinical trials of medicinal products for human use will only apply six months after the publication of notice by the European Commission that the EU portal and the EU database are fully functional, which is expected in 2020. The EU portal and the EU database are digital systems for the transmission of data and information in connection with clinical trials. They are intended to enable and facilitate collaboration between the competent authorities and communication between sponsors and member states as well as providing the general public a search function for obtaining information on individual clinical trials. In this way, information technology will assist the application of law – namely clinical trial law. Conversely, the law’s dependence on IT is likewise increasing, as is emphatically evidenced by the fact that Regulation (EU) No 536/2014 will not be applicable until the EU portal and the EU database are deemed functional. Moreover, digitization brings with it new regulatory topics. The following article provides an overview of the upcoming developments in pharmaceutical law as a result of digitization, algorithmization and artificial intelligence (AI).

¹ Extract from Dettling/Krüger, Digitization, Algorithmization and Artificial Intelligence in Pharmaceutical Law, originally published with footnotes in the German legal journal “Pharma Recht” (PharmR) 2018, 513 et seq.
“Thanks to ‘deep learning’, AI will increasingly outperform humans in specialized fields.”

Gerd W. Stürz, GSA Marketsegment Leader Life Sciences, Health & Chemicals

Digitization, algorithmization and artificial intelligence (AI)

General definitions and technical possibilities

Rapid advances in hardware and software performance have enabled IT to go far beyond the mere display and processing of information in electronic form, i.e., “classical” digitization in the strictest sense of the word. While only recently, music composed and played by humans and stored in digital form as music CDs was merely replacing analog vinyl records, the charts are now being scaled by hits produced by artificial intelligence. AI is software that learns and makes decisions by itself (autonomously). It is capable of independently performing complex selection processes involving a wide range of data and emotional aspects, and implementing these with the help of software-controlled machines. Unlike early algorithms that represented electronic selection processes determined by their human programmers, modern learning algorithms are capable of autonomously identifying patterns, classifying information and thus “learning” and selecting, i.e. making decisions by means of neuronal network structures with feedback mechanisms on the basis of large amounts of data (“big data”) with which they are “fed” and “trained”. Such data can comprise numbers, text, images, speech and other information. Like humans, AI is able to engage in abstract “thinking” by comparing as much reference material (data) as possible. If the electronic execution of selection processes is understood to mean “algorithmization” and digitization in the broadest sense, AI with its specific learning algorithms and autonomous electronic selection decisions represents the most ambitious discipline. By gaining independence, AI also breaks free from the shackles imposed by human programmers, triggering a major debate about the human control over AI in the political, ethical and legal arena.

Recent experience has shown that AI boasts an enormous learning curve. Thanks to “deep learning”, AI will increasingly outperform humans, at least in certain specialized fields. Since 1997, even chess programs without any autonomous learning functions have been able to beat human world champions. In 2016, the computer program AlphaGo used learning algorithms and AI to beat the world’s best human players in the ancient Japanese game of Go. Until then, Go had been considered the benchmark for the performance of AI. While in 2013, a textbook on artificial intelligence had claimed that “we humans are still miles ahead of today’s computer programs” given that all electronic Go programs had great difficulties recognizing whether a group of stones was dead or alive (i.e., active or inactive in the game) or in between, the statement had to be revised in the next edition of the same textbook just three years later. Against this backdrop, it is no longer possible to automatically relegate to the distant future the possibility of “strong AI” or “superintelligence” - i.e., AI that is not only superior to humans in specific areas in the form of “weak AI”, but as a generalist. This holds especially true in view of the fact that “deep learning” also means that AI can be used for the self-optimization of algorithms. It stands to reason that such “deep programming” will by far outpace and outperform human programmers. Taking into account the originally programmed, “motivating” objectives such as the maximizing of certain scores (“deep maximizing”), the fields of science, politics, ethics and law are increasingly focusing on the arguably greatest challenge humans have ever faced - the prevention of a “takeover of power by machines” and the formulation of regulatory boundaries for AI in order to retain human control.
General ethical requirements and controlled AI ("CAI")

A growing number of people – including among tech pioneers in particular – are drawing attention to the need for defining limits for the programming of AI and the necessity for “digital ethics”, i.e., controlled AI (CAI). AI, that is the “leap from computing to cognitive informatics”, raises fundamental questions with regard to the control of the consequences of technology. Accordingly, national parliaments are intensively debating the subject of AI. The magnitude of AI’s impact can be seen in the fact that the 2017 robotics resolution of the European Parliament suggests the establishment of a “status of an electronic person” or an “electronic personality” for cases in which “robots” make autonomous decisions or otherwise interact with third parties independently. At the same time, the resolution also underscores the need for installing “kill switches” in such systems, emphasizing that intelligent robots are not biological life.

In this field, the EU Parliament has requested the European Commission to submit a proposal for a regulation on civil law rules governing robotics in order to control the risks associated with AI and “intelligent robots”. In particular, the EU Parliament has provided for the following rules:

1. An EU Agency for Robotics and Artificial Intelligence should be established.
2. A comprehensive EU registration system should be introduced for advanced robots.
3. Robots should serve humanity.
4. Robots should complement human capabilities, not replace them.
5. Robots should be identifiable as robots when interacting with humans.
6. Humans should have control over robots at all times. Maximum transparency should be required in the programming of robotic systems, as well as predictability of robotic behavior.
7. Robots should be equipped with a “black box” that records data on every transaction carried out by the machine, including the logic that contributed to its decisions. The robot’s decision-making steps should be amenable to reconstruction and traceability.
8. Robot actions should be reversible in order to allow users to undo undesired actions and get back to the “good” stage of their work.
9. Opt-out mechanisms (kill switches) should be integrated in robots.
10. The guiding ethical framework for robots should be based on the principles of beneficence, non-maleficence, autonomy and justice. Moreover, it should be based on the principles and values enshrined in Article 2 of the Treaty on European Union and in the Charter of Fundamental Rights as well as on other underlying principles and values of the Union law and on existing ethical practices and codes.
Digitization, algorithmization and AI in pharmaceutical law

Besides the legal system in general, especially medical and pharmaceutical law around the globe is faced with great challenges due to the development of AI. In the field of medicine, much is expected from AI. The digitization in the field of medicine opens new doors in the diagnosis and therapy of diseases. Medical experts expect the role of physicians to change due to rapidly progressing developments in the field of “machine learning”, the ongoing collection of personal medical data by healthy individuals and patients (“self-tracking”) and new methods for gaining insight by analyzing huge amounts of data from standard healthcare (“big data”). Health care payors in particular hope that the digitization of the healthcare sector will increase the efficiency and cut costs.

While the application of specific “weak AI” in certain areas has become an indispensable part of our daily lives - e.g., in the field of mobility and e-commerce – even the use of weak AI in the medical and pharmaceutical industry poses new challenges for government authorities and professional bodies. In view of their direct relevance to human life and health, which both the European Union and the constitution place at the top of their value systems, decisions in the field of medicine and drug supply need to fulfill stringent qualification and monitoring requirements. This highlights in particular the need for control of AI and thus for digital ethics and regulatory law governing AI.

Given the primacy of human life and health and the applicable strict approval requirements with respect to quality, safety and monitoring, AI-based autonomous electronic selection processes represent a major challenge in the context of specific medical examinations and patient treatment. The ECJ has ruled that, not only software used for operating medical products, but also software that is used for decisions for diagnostic or therapeutic purposes qualifies as a medical device and must therefore be certified according to medical devices law (known as “software as medical device”, SaMD). In particular, software whose functionality enables the use of patient data in order to identify details such as contraindications, interaction of drugs and overdosing in the context of patient care is deemed a medical device, even if the software does not directly act in or on the human body.
Software used to take decisions that may cause death or an irreversible deterioration of a person’s health must be classified as a class III medical device pursuant to Rule 11 of Annex VIII of the Medical Devices Regulation (EU) 2017/745, which will apply from May 2020. Pursuant to Art. 61 (4) sentence 1 of the Medical Devices Regulation (EU) 2017/745, the certification of class III medical devices requires a clinical trial, which in turn needs to be approved by the authorities. Moreover, the use of software in new examination and treatment methods funded by statutory health insurance requires the approval of the Joint Federal Committee pursuant to Section 135 of the German Social Code V (SGB V). Pursuant to Section 2 (3) sentences 2 and 3 of the German Medical Devices Act (MPG), combinations of medicinal products and medical devices as an integral product are subject to the regulations of the German Medicinal Products Act (AMG) and thus to the statutory requirement for marketing authorization by the competent authorities pursuant to Art. 3 (1) of Regulation (EC) No 726/2004 and Sections 21 et seq. AMG. In this area, medical devices law applies only insofar as the medical device must meet the basic requirements pursuant to Section 7 MPG that concern safety and performance-related product functions. Among the basic requirements that must be met by medical software and medical devices that are, or can be, integrated in IT networks via networking interfaces are their security, including cybersecurity, ensuring comprehensive shielding against accidental or intentional manipulation of the respective medical product’s operation and the resulting danger to patients, users or third parties.

On the one hand, the application of AI systems like IBM’s Watson for supporting medical diagnosis and therapy decisions is being tested and has already delivered promising results. On the other hand, German authorities and the sector’s self-regulation bodies will continue to take a critical stance on the use of AI that autonomously makes decisions and thus replaces the physician or pharmacist as long as the methodology underlying the electronic selection lacks transparency. Therefore, the certification of such systems under medical product law or their approval under pharmaceutical law still appear difficult at present. The “10 commandments” from the robotics resolution of the EU Parliament (see point 2, top left) can provide guidance in this area. In April 2018, the US Food and Drug Administration (FDA) approved for the first time a medical device with image-analyzing AI software.

The above overview shows how deeply and diversely even pharmaceutical law will be changed by digitization, algorithmization and artificial intelligence. The protection of personal data is not the only area in which new challenges will arise. Questions concerning the ownership of data as the “gold of the 21st century” under civil law and intellectual property issues are equally significant. Most importantly, however, the regulation of artificial intelligence will form a new legal field and constitute a critical task for lawmakers in a bid to benefit from the opportunities of this power technology while controlling its risks with “controlled AI” (CAI). In the field of pharmaceutical law, this challenge will be amplified due to its direct impact on human life and health. Though this is a technical subject, lawyers who specialize in pharmaceutical law need to be more willing to examine, not only new regulatory aspects, but also technological innovations. Together with policymakers, legal experts play a key role in ensuring that the “revolution in biotechnology and information technology” progresses in an ethically acceptable direction.
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