ARTIFICIAL INTELLIGENCE AND PROTECTION OF INDIVIDUAL RIGHTS IN THE FIELD OF PHARMACY

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Abstracts.

The article is devoted to the study of trends and prospects for the use of artificial intelligence in the organization of pharmaceutical business. The relevance and significance of the research topic is substantiated. The key advantages of integrating artificial intelligence and other end-to-end technologies into the practice of pharmaceutical organizations in the context of drug discovery and development processes are considered. The author analyzes the trends in the use of artificial intelligence to improve (simplify and reduce the cost of) production, analytical, research and other business processes of a pharmaceutical organization, and provides practical examples. The article provides a brief overview of analysts' and experts' forecasts regarding the application of artificial intelligence in the pharmaceutical business organization in the short term. It is established that in order to realize these forecasts and, in general, to accelerate the industrialization of the pharmaceutical industry with the help of end-to-end technologies, as well as to stimulate the use of artificial intelligence to improve the organization of pharmaceutical business, a number of measures should be taken; to increase the availability of medicines in the pharmaceutical market, to ensure a higher level of compliance with regulatory requirements, as well as to increase the medical effectiveness and social significance of innovative developments in the field of circulation of medicines in the context of the

The author analyzes possible threats to the right to privacy arising from the use of artificial intelligence and suggests ways to eliminate them by improving the legislative mechanisms for personal data protection.

Protection of the right to privacy is becoming particularly important due to the rapid development of technology. Massive collection of personal data via the Internet and mobile applications, data analysis using AI, the use of biometric technologies, as well as the increase in cybercrime and illegal surveillance pose serious threats to an individual's privacy. Therefore, there is an urgent need for further research to ensure the right to privacy in the context of artificial intelligence. This right is enshrined in both universal and regional international agreements, such as the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the Convention for the Protection of Human Rights and Fundamental Freedoms, the Charter of Fundamental Rights of the European Union, and others. Society is increasingly aware of the importance of protecting confidentiality (privacy) and the potential risks in case of its violation. The use of personal data for government or commercial purposes raises ethical questions about the boundaries of what is permissible and inviolable. Increasing globalization requires coordinated approaches to privacy protection at the international level. The adoption of regulations such as the GDPR and the Artificial Intelligence Act in Europe, as well as the CCPA and CPRA in California, confirms the importance of personal data protection and the right to privacy.

Keywords: Artificial intelligence, pharmaceutical business, pharmaceutical industry, biotechnology, end-to-end technologies, industrialization of the industry, medicines, omnichannel, pharmaceutical organizations, industrialization, pharmaceutical market, medical effectiveness, social significance, innovative developments, right to privacy, confidentiality, personal data.

Trends and prospects for the use of artificial intelligence in the field of pharmacy

At the present stage, artificial intelligence is recognized as one of the priority areas of information technology research, a catalyst for industrial breakthroughs, which is an indicator of a new era called the Fourth Industrial Revolution (Industry 4.0). In 2020, the global artificial intelligence market was estimated at USD 62.3 billion, and in recent years it has been growing at an average annual rate of 40.2%. This is largely driven by ongoing research and technological solutions initiated by digital corporations, which makes it possible to introduce advanced technologies into various industries such as automotive, healthcare, retail, finance, manufacturing, etc. The idea of integrating artificial intelligence into certain spheres of human life is changing the public consciousness, allowing us to more clearly define the framework of strategic vision, expand the boundaries of strategic thinking, and see prospects in those areas of production and consumption where progress is a necessary good.

The use of artificial intelligence is especially relevant for such an important industry as the pharmaceutical industry; it is the ability of this industry to respond to social demand in a timely manner that allows it to maintain not only the healthcare, medicine, insurance, etc. directly related to it, but also indirectly related areas, including the chemical industry, mechanical engineering, biotechnology, etc. Of course, such responsibility implies an uncompromisingly precise approach that eliminates the uncertainty factor (inaccuracies, errors, conventions), and it can only be realized with the use of advanced (end-to-end) technologies. A developing industry that uses scientific and technological innovations and smart technologies is able to ensure the rapid and efficient production of medicines and other drugs, vitamins, enzymes, antibiotics, etc. in critical situations for medicine and healthcare. For example, the COVID-19 pandemic, which required maximum effort from research centers to find, develop and quickly introduce new anti-coronavirus drugs.

In recent years, pharmaceutical companies around the world have been using machine learning algorithms and AI-based tools to simplify drug discovery and development processes. Moreover, according to MIT, a pharmaceutical company's costs for the production of a single drug range from USD 161 million to USD 2 billion to go through the full clinical trial process (which lasts approximately 10-15 years) and obtain FDA approval[1]. These are two of the main reasons why pharmaceutical companies are increasingly adopting artificial intelligence and other end-to-end technologies to make drug discovery and development easier and cheaper, as well as to increase the efficiency of creating more affordable, in particular innovative drugs and treatments. Experts note that in the future, the use of artificial intelligence can reduce drug development time by 50-60%, increase the chances of successful clinical trial results (currently the average is 13.8%), and more effectively reprofile drugs by identifying new molecules. Thus, in an environment where the cost of developing new molecules is steadily increasing and the likelihood of their successful commercialization is steadily decreasing, it is important to increase efficiency, work on specific target areas, apply smart technologies, big data analysis, and engage partners.

However, it is important to understand that the mechanism of applying end-to-end (smart-, digital-) technologies is not limited to the sphere of the final product (as a result of research), the benefit created with their help. Solutions such as artificial intelligence and the Internet of Things

have a much broader potential, which is manifested in the scale of business tasks they can solve. Thanks to the use of artificial intelligence, the only technology capable of making decisions and communicating with humans, management has received high-quality professional tools for monitoring, forecasting, management, and control.

According to surveys conducted in 2020 by OpenText, interest in the practice of integrating artificial intelligence into the production processes of pharmaceutical organizations has increased to 85% in 2020 compared to 47% in 2018[2]. In our opinion, this trend can be explained by the fact that artificial intelligence significantly improves quality control, changes the main stages of trial design, manages material and technical resources more efficiently, reduces waste, facilitates automation of logistics processes and balances demand in supply chain planning. Of course, in addition to significantly increasing the return on investment by limiting human intervention in the production process (where practical), artificial intelligence also minimizes the likelihood of human error.

A striking example is Pfizer Corporation, which has implemented analytics and neural network technologies at one of its facilities in the UK to improve current production processes. This allowed the company to increase the speed of the production line by 21%, reduce downtime, and increase the overall efficiency of the equipment by 10%. In addition, the company was able to improve the detection of quality defects, optimize machine performance, and fully ensure the implementation of compliance (risk management) at the enterprise[3].

Artificial intelligence is also completely changing the way we think about analytics, which is an integral part of the entire set of business processes of a pharmaceutical organization; it is about algorithms designed to read, group and further interpret data for research and experimental purposes. At the present stage[1] many clinical trials are still based on "paper diaries," in which patients record the time they took their medications, which drugs they took at the same time, and any adverse reactions they experienced. Artificial intelligence is able to collect and interpret everything from handwritten notes and test results to environmental factors and scan images. For example, in 2020, Pfizer organized a hackathon (developer forum) to test the possibility of using artificial intelligence to automate the process of launching a trial in order to reduce the duration of the trial cycle and reduce costs. During the event, the corporation's experts clearly demonstrated that artificial intelligence is able to process and interpret data in unstructured documents (for example, in a trial protocol), identify inconsistencies in manually entered trial data, and digitize data elements in key documents so that they can be transferred to further systems without human intervention. The benefits of using artificial intelligence thus include faster research and cross-referencing of data, as well as combining and extracting results into easy-to-analyze formats. A Cognizant study found that about 80% of clinical trials fail to meet registration deadlines, and a third of all Phase III clinical trial terminations are due to registration difficulties[4].

Artificial intelligence plays a colossal role in sales and marketing analytics, as it enables the simultaneous engagement of all sales channels—this refers to the principle of omnichannel marketing. AI-powered multichannel interaction solutions, used for analyzing various data sources (including socio-economic, demographic, geographic, medical, and sales data), can predict how, when, and in what way to interact with suppliers, patients, and practicing physicians. This makes it possible to deliver personalized content, for example, through mobile applications. Moreover, as demonstrated by the practices of companies such as Biogen, AI-driven omnichannel marketing can provide recommendations to marketing and sales representatives regarding next steps, appropriate channels, and personalized content for engaging with external stakeholders in the pharmaceutical ecosystem. For instance, Biogen has developed an internal search system that

utilizes neuro-linguistic programming mechanisms to help pharmacy organizations (or other entities distributing the company's products) quickly find answers to potential consumers' questions about its products. A key indicator of the effectiveness of this solution is the steady growth in sales volumes.

Overall, it can be said that the use of artificial intelligence in the pharmaceutical industry is no longer considered a process of the "distant future"; this is evidenced by the progressive practices of well-known pharmaceutical corporations such as Pfizer, Roche, Novartis, Johnson & Johnson, Merck & Co., Sanofi, Gilead Sciences, and others. According to Deloitte forecasts, the pharmaceutical industry is gradually transitioning to an optimized operational model to attract funding and improve the efficiency of integrating smart technologies, particularly artificial intelligence. The industrialization of the sector will increase productivity across all functions and geographic regions, while pharmaceutical companies will go through three stages of development: codification and standardization of business processes, their automation, and only then—the integration of AI and machine learning systems for further growth and productivity. Priority will be given to transformation during the technologization of financial and operational processes, aimed at more effective compliance, optimization of pharmaceutical activity organization, and the development and discovery of new (innovative) drugs. Such significant productivity growth will positively impact regulatory compliance and enhance the predictability of core business processes in pharmaceutical manufacturing as a business entity. Organizations that demonstrate best practices in technical modernization will contribute to optimal consolidation of the sector. As a result, the development time for new drugs will be reduced by approximately one-third, and productivity will increase by 40%.

Structure of the Life Cycle of Medicinal Products and the Role of Digital Solutions at Its Stages

The study and optimization of the life cycle processes of medicinal products (LCMP) have been addressed by many researchers both in Ukraine and abroad[5].

The life cycle of medicinal products (LCMP) begins with research and development—both pharmaceutical and pharmacological. At this initial stage, pharmacological studies are conducted, including the search for the composition of a potential medicinal product (MP), the determination of its biological activity based on the properties of its components, and the development of a production technology[6].

The development stage is usually one of the most costly and time-consuming phases in bringing a new medicinal product (MP) to market. At this stage, applications may be submitted for the protection of intellectual property created during the development of the MP. For the subsequent stages of the life cycle, manufacturing should already be organized (technology transfer), and the batches of the MP produced for testing must be technologically equivalent to those intended for industrial production. During the pre-registration period, efforts are made to identify and select an optimal brand name for the developed MP, and trademark registration may also be carried out.

To prepare data on toxicity and determine the appropriate dosage of the developing medicinal product, preclinical studies (PCS) must be conducted using in vitro and in vivo models. Globally, these studies are governed by Good Laboratory Practice (GLP) standards. Compliance with these standards is essential for the international recognition of research results[7].

Manufacturing considerations involve not only presenting the active pharmaceutical ingredient in a consumer-friendly form but also selecting the necessary excipients for this purpose. Very often, it is the composition of the excipients that determines the quality of the future medicinal product and its potential side effects. The production of medicinal products is regulated by a quality system specific to the pharmaceutical industry — Good Manufacturing Practice (GMP). This standard governs all stages of pharmaceutical manufacturing — from the procurement and control of raw materials to the quality assurance of the final product.

To ensure the proper quality of medicinal products, it is essential to comply with the standards for their storage and transportation, as defined by Good Storage Practice (GSP). These standards may be implemented by both the manufacturer and the distributor.

Wholesale distribution is also regulated by the relevant standard — Good Distribution Practice (GDP). At this stage, the provision of medicinal products (MPs) for state needs is also considered, particularly in the context of medical supply for the Armed Forces.

The next step in delivering MPs to the end user is retail distribution, which is regulated by Good Pharmacy Practice (GPP). This system of standards was developed by the International Pharmaceutical Federation (FIP) and is recommended for implementation by the World Health Organization (WHO).

Medical use is the primary purpose for which medicinal products are developed and represents a key stage in their life cycle. MPs are used as prescribed by healthcare professionals in outpatient or inpatient (hospital) settings, or independently by patients (responsible self-medication with over-the-counter drugs). Digital technologies can be employed to assess the pharmacoeconomic efficiency of using medicinal products compared to other treatment methods.

The main therapeutic effect of an MP, for which it is applied in clinical practice, may be accompanied by side effects (any actions other than the intended one, including adverse reactions and post-vaccination complications) or by a lack of declared efficacy. Therefore, the medical use of MPs is accompanied by monitoring of their safety and effectiveness, governed by the standards of Good Pharmacovigilance Practice (GVP).

In the case of expiration or the identification of substandard quality in a specific batch of an MP, disposal must be carried out in accordance with the rules set by legislative acts and executive authority regulations.

At all stages of the life cycle of medicinal products (LCMP), the process of informing pharmaceutical professionals and other participants in the medicinal products circulation system (MPCS) about compliance with good practice standards is crucial. The effectiveness of transitions between stages largely depends on the informational interaction among stakeholders.

To ensure compliance with quality standards, corporate information systems (CIS) are used, specific to each stage of the LCMP. These systems vary widely and are often unique to each organization. Both proprietary systems and commercial products adapted to specific needs may be used.

In international practice, there are also standards governing the requirements for CIS within the framework of the MPCS.

The exchange of digital data between MPCS entities and regulatory authorities requires the existence of unified rules for describing medicinal products and all related information regarding their circulation. This includes the use of standardized terminological directories.

Many solutions are implemented at the level of components within medical information systems (hereinafter — MIS) of individual healthcare institutions or at the regional level — as part of regional medical information systems (hereinafter — rMIS).

A wide range of both general-purpose and specialized software is used for this purpose. General software includes office applications, data analysis and statistics programs, ERP systems (Enterprise Resource Planning), and various automated process control systems (hereinafter — APCS). Also common across the entire life cycle are Customer Relationship Management (CRM) systems, which help manage interactions with clients.

The life cycle of pharmaceutical products consists of a series of strictly regulated phases. Laboratory research is conducted at many of these stages. Various corporate information systems (CIS) can be used to carry out these processes. For instance, during preclinical studies, data on test animals, observed effects from biologically active substances, and information about the samples and materials used are recorded in such systems.

Laboratory Information Management Systems (LIMS) manage laboratory data. Key functions of LIMS include: test management, sample and material tracking, personnel management (integration with HR systems), assignment of responsible staff, equipment tracking, personnel training, quality management system audits, standard operating procedures, and requests for reagents and materials. These systems take into account employee qualifications, experience, and equipment readiness, including calibration status. Test results are calculated using pre-entered formulas, and each method must be entered into the system before testing begins.

A Clinical Trial Management System (CTMS) addresses one of the most critical objectives: ensuring strict adherence to project timelines. According to industry experts, a single-day delay in bringing a medicinal product to market may cost a pharmaceutical company approximately $1 million. The CTMS helps minimize the risk of such incidents. This system allows real-time 24/7 monitoring of clinical trials from anywhere in the world. It enables tracking of actual time spent on the project, task progress, and adherence to deadlines—both for the overall project and for individual tasks.

The collection of clinical trial results can be carried out electronically using electronic data capture (EDC) technology. During clinical trials, it is preferable to completely eliminate the stage of manually transferring data from paper records. A recent advancement in this area is the Direct Data Capture (DDC) approach. It allows primary data to be entered directly and some of them to be identified as fields of the Case Report Form (CRF) for the purposes of the clinical trial, directly at the point of care by research organization staff, for example, using an electronic tablet. An important element of the DDC concept is that clinical evaluations and other output data are entered during the visit, not later. To be compliant, the DDC system and application must be configured according to legal requirements and ICH GCP standards (Good Clinical Practice), verified, secured, and supported. GCP requires that all records, changes, and deletions in the system be fully traceable through an audit trail. This also applies to the DDC system. EDC systems already allow direct data entry if this is specified and approved in the trial protocol. Thus, the presented electronic data system is already largely permitted by regulatory documents. CTMS are widely used by large pharmaceutical companies and Clinical Research Organizations (CROs) conducting clinical trials. [8].

The need for corporate information systems (CIS) is largely driven by the necessity to comply with international standards of good practice, such as GLP, GMP, and GaMP (Good Automated Manufacturing Practice). Compliance with these requirements is essential, for example, for the recognition of laboratory research results at the international level.

Currently, most developed countries have completed the transition from paper-based regulatory dossiers to electronic formats. For this purpose, an electronic modification of this standard is used — eCTD (Electronic Common Technical Document). Since June 2003, this

format has been accepted in the European Union alongside paper submissions. From January 2013, the centralized procedure for drug registration in the EU has been fully transitioned to the eCTD format. As of March 2014, it has been accepted as the only permissible format. eCTD was adopted by the FDA (U.S. Food and Drug Administration) on January 1, 2008, as the mandatory format for submitting electronic information. The requirement for an electronic dossier in eCTD format became mandatory on May 5, 2017. Thus, the process of submitting a dossier in electronic format has shifted from being an auxiliary process to a key one for completing the necessary procedures.

At the level of the EAEU (Eurasian Economic Union), the decision of the EEC Council No. 78 of November 3, 2016, "On the Rules for Registration and Expertise of Medicines for Medical Use" has been adopted, which approves the requirements for the application and regulatory dossier in the Common Technical Document (CTD) format. Additionally, the EEC Collegium Decision No. 79 of June 30, 2017, "On the Requirements for the Electronic Form of Applications and Documents of the Registration Dossier Submitted during the Registration and Expertise of Medicines for Medical Use" was approved, which specifies the electronic format for submitting applications and dossiers in the form of the electronic Common Technical Document (eCTD). [9].

It is also necessary to consider the possibility of applying a large number of different categories of specialized Corporate Information Systems (CIS) created to automate specific stages of the drug lifecycle (DLC).

Concept of a Unified Information Space in the Field of Medicinal Products Circulation

Currently, one of the most relevant directions for improving the provision of medicines to the population is the implementation of digital solutions at the respective stages of the drug lifecycle (DLC). The greatest interest lies in systems for monitoring the movement of drug packaging, as well as their procurement, particularly through state funding. In this case, cataloging and unambiguous identification of drugs become of primary importance. It is equally important to accurately identify drugs at earlier stages of the lifecycle. A clear description that avoids misleading consumers should be created at the registration stage. Later, this data will be used both during civil circulation and in the framework of medical use, for example, in pharmacovigilance systems.

To achieve consistency of information, it is necessary to create a unified source of information about medicinal products (so-called master data). In this regard, improving the drug registration process by transitioning to a registry model, instead of issuing paper registration certificates (hereafter referred to as RC), is advisable.

It is also reasonable to implement the requirements of the ISO IDMP (International Organization for Standardization, Identification of Medicinal Products) standards for the description and coding of drugs. A structured description of active pharmaceutical ingredients (APIs), the drugs they are part of, and the product items considering the form of these medicines has been developed. A structured presentation of regulatory documentation (RD) and instructions for medical use (IMU) of medicines is also necessary.

With the help of drug identification (according to IDMP standards), several international organizations such as EMA, FDA, and ISO have developed a set of standards for the formalized description of medicinal products and other medical products, primarily for the regulation of the drug circulation system (DCS). The work on implementing these standards into drug cataloging practices is of interest to specialists from many countries[10].

In the United States, the RxNorm system[11] it has existed for several decades and is often referred to as the standard reference information system (SRI) for medicinal products (MP) [12].

It is a tool for supporting semantic interoperability between drug descriptions and databases containing information about medicinal products (MP). Unified names of active ingredients are used to denote both generic and original medicinal products. The information is presented at various levels of detail, for example, by providing data about the MP, dosage forms (DF), and the MP itself. The system includes attributes such as unique identifiers related to the IDMP concept, for example, unique ingredient identifiers (UNII) or national drug codes (NDC). [13].

Although RxNorm is a CIS specific to the United States, the ISO IDMP standard was created to standardize drug information worldwide. Initially, this methodology was developed in the context of pharmacovigilance. Later, it was extended to all other areas of healthcare where drug information is required, such as for prescribing and dispensing medications. [14].

To ensure broad interaction between global regulatory and medical communities, these standards were developed and published under the auspices of ISO (International Organization for Standardization) with the participation of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), HL7 (Health Level 7), as well as other international stakeholders and experts.[15].

ISO IDMP consists of five separate standards, published in 2012, which describe data elements and their structural relationships for the unique identification and exchange of digital data.

These standards cover various aspects of medicinal product description: the name of the medicinal product (INN, group or chemical name), the substances it contains, the pharmaceutical product (route of administration, activity), the marketing authorization, clinical data, packaging, manufacturer, and other relevant information.

The standards describe primary identifiers: a set of unique identifiers for medicinal products, which complement the registration number assigned by the competent authority.

These identifiers are intended for accounting purposes and to enhance patient safety, as they allow for the unambiguous identification of medicinal products worldwide.

The standard defines the concepts necessary to establish the relationship between identifiers such as PhPID – Pharmaceutical Product Identifier, MPID – Medicinal Product Identifier, and PCID – Medicinal Product Package Identifier, with corresponding registration numbers assigned by the competent authority.

In the European Union, EMA is implementing the IDMP standards within a phased program. This program is based on four areas of knowledge in pharmaceutical industry regulation processes: substance, product, organization, and referential data (SPOR, Products, Organisations, and Referential). The dictionary management system was launched in June 2017 to provide essential data in electronic submission forms and contains over one hundred lists of controlled dictionaries to describe product attributes, such as lists of dosage forms, units of measurement, and routes of administration. These include standard term lists from the European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe, compliant with ISO 11239 and ISO 11240 standards. For substances, the G-SRS (Global Substance Registration System) was selected and adapted as a basis, and it is being tailored to European requirements (EU-SRS – European Substance Reference System).

The EAEU has established a unified system for NCD (Normative-Reference Data). It consists of directories approved and adopted by the Eurasian Economic Commission and is used for digital data exchange. It is also applied for the creation of joint registries and information systems that facilitate data processing and submission.

The structure, formation principles, participants of the EAEU unified NCD system, as well as the procedures for managing system resources and the management of NCDs within the EAEU, are defined by the Regulation on the Unified System of Normative-Reference Information of the Eurasian Economic Union.

The methodology for developing, maintaining, and applying directories and classifiers within the resources of the Unified NCD System of the EAEU is approved by the Decision of the Board of the Eurasian Economic Commission. The authorized bodies of member states act as operators of the Unified NCD System of the EAEU.

Regarding specific types of directories and classifiers that are part of the resources of the Unified NCD System of the EAEU, the operator function may be performed by the Commission.

Users of the Unified NCD System of the EAEU include the departments of the EEC, authorized bodies of member states, as well as other government authorities, local government bodies of member states, third countries, international integration associations, international organizations, and legal and physical entities.

The Practice of Using Electronic Dossiers in the Examination of Medicinal Products

Today, the most valuable resource in the pharmaceutical industry is scientific technologies and high-tech products as a result of their practical application. Modern medicinal products demonstrate significantly higher effectiveness compared to those that were allowed on the market 20 or more years ago. At the same time, markets in the EAEU countries feature medicinal products that, in certain cases, have already been withdrawn from circulation in Western countries. This is largely related to the difference in the level of social well-being and the ability to provide consumers with only the most modern drugs with maximum effectiveness and minimal side effects. The presence of less effective but significantly cheaper medicinal products creates significant differences in therapy costs for patients in developing countries and countries with developed economies.

Another aspect of this issue is that new medicinal products registered and used in Western Europe and the United States are currently absent from the pharmaceutical market of the EAEU. In several cases, treatment for certain diseases is impossible without foreign medicinal products, which leads to the necessity of individual acquisition of a medicinal product that is officially absent from the market. Such a procedure is possible only in situations that threaten the life and health of the patient and is carried out based on the decision of a medical commission.

The preservation of the production potential related to pharmaceutical supply within the country's territory also has social and political significance. Taking into account the experience of the 20th century in the creation and use of biological weapons, one cannot rule out the possibility of such aggression from one state towards another. Work on protection from such threats is ongoing abroad. If pharmaceutical supply is fully entrusted to a more efficient manufacturing state, the situation could become catastrophic in the event of biological aggression or a natural epidemic, and at the same time, an embargo is imposed on the supply of necessary protection or treatment products.

Thus, the integration of the pharmaceutical market of the EAEU has several goals that must be achieved simultaneously without hindering each other. First, this involves the revision of the entire list of medicinal products registered in the EAEU member states. Second, it is the harmonization of dossier requirements with those set by ICH and recognized by EMA, FDA, and other international regulators in the global medicinal products circulation system. As a result, manufacturers of new high-efficiency medicinal products will find it easier to register their

products in the EAEU market. Additionally, the attractiveness of this market for them will increase due to a larger consumer base within the EAEU compared to each member state separately. The third goal is to maintain the possibility of conducting the maximum number of productions within the territories of EAEU member states.

Returning to the issue of market integration among different countries, at the current stage of economic development, it is important to highlight digital technologies in general, and the Internet in particular. Communication technology plays the role of a mediator in uniting different states. At the same time, the costs of such a mediator are significantly lower than the margin included in the transaction amount. Business processes within the EAEU are built based on the principles of digital data exchange. The Integrated Information System of the Eurasian Economic Commission (EEC IIS) describes and standardizes the rules for the interaction of participants in the integrated market. Unlike previous periods in human development, the digital era does not require the physical movement of objects for information exchange via digital data. Digital information is transmitted through the Internet network almost instantly compared to other methods of data transmission.

For the exchange of digital documents stored in electronic form without human involvement in recognizing the text of these documents, all documents must be prepared in a formalized format, meaning one that can be processed by the software tools of all participants in the exchange.

Preparing a dossier for submission to the registration procedure involves forming a package of necessary documents in electronic form, either in the eCTD format or other standards required by the regulatory authorities of the submitting country. Effective management of validated and compliant dossiers for electronic submission is a comprehensive process that requires the use of specialized software.

Use of Machine Learning and Artificial Neural Networks in the Life Cycle of Medicinal Products

One of the directions for automating the analysis and forecasting of various phenomena can be considered the application of AI, which works with big data, as a more efficient replacement for humans in certain types of analytical activities. Computational systems today are capable of solving more and more processes that were previously solely within the competence of humans. Moreover, they do this with higher quality and, in many cases, more economically efficiently. A wide field exists within the development of AI — machine learning (ML). It studies methods for building algorithms capable of learning independently. This is necessary when there is no clear solution to a particular problem. In such a situation, it is more appropriate not to search for the right solution manually, but to create a mechanism that will generate the method of its search on its own. A neural network models the functioning of the human nervous system, a feature of which is the ability to learn independently, taking into account previous experiences. Thus, with each iteration, the system makes fewer mistakes.

ML technologies are also relevant for the pharmaceutical industry. They help reduce the risk when making decisions during the development of new medicinal products and avoid failures at later stages of creation. Based on these technologies, analytics and computer modeling are performed. They are successfully used to analyze large volumes of data when assessing the risk of increasing resistance of infectious disease pathogens to antibacterial drugs. In the pharmaceutical and medical fields, databases are being created that can be useful for training neural networks. It

is expected that the accumulation of up-to-date information on health status and disease treatment will be a catalyst for the active use of AI in pharmacology and pharmacy.

The lack of necessary medicinal products on the market is a global healthcare problem. In this regard, the use of machine learning (ML) technologies is of great importance for improving this problem area.

For example, since 2016, a target group created by the EMA has been considering issues of availability, including medicines that are authorized but not sold, as well as supply chain disruptions, to improve the continuity of medicinal product supplies across Europe. This is part of EMA's efforts since 2012 to improve processes to eliminate shortages of medicines caused by violations of good manufacturing practice (GMP)[16]. According to the FDA, drug shortages can arise from various causes, including manufacturing issues, quality problems, delays, and discontinuations. Manufacturers provide the FDA with a significant amount of information regarding drug shortages, and the agency works closely with them to prevent or mitigate the impact of such shortages. In October 2019, the FDA published the report titled "Drug Shortages: Root Causes and Potential Solutions"[17], the report aimed to identify the root causes and provide recommendations to help prevent and mitigate drug shortages. The recommendations were based on information gathered from public and private stakeholders during the Drug Shortages Task Force meeting held in November 2018, as well as an analysis of FDA data and published research [18].

One of the most advanced methods for monitoring drug shortages is the implementation of digital primary data collection technology. This enables the use of subsequent machine learning systems based on artificial neural networks (ANNs) for data analysis.

Machine learning is a technology that allows AI to automatically learn from past experience without the need for explicit programming[19].

Its application can be found in virtually all areas of human life. For it to function effectively, it is necessary to create a database organized into clusters with cause-and-effect relationships between them. Leveraging the experience and knowledge of the scientific community regarding methods of interaction and the establishment of dependencies between data points allows for more accurate deep learning results.

Promising outcomes have been demonstrated using artificial neural network (ANN) models for the diagnosis of mental disorders[20], Parkinson's disease[21] and Huntington's disease[22]. Multilayer perceptron models (a mathematical or computer model of information perception) are used to predict the risk of osteoporosis[23]. Conclusions and generalized regression are used for the diagnosis of hepatitis[24]. A neural network is a series of algorithms designed to identify underlying relationships in a dataset through a process that mimics the functioning of the human brain.

To develop and bring to market a new unique medicinal product or a new drug combination, pharmacological and toxicological studies must be conducted. These include confirmation of quality, efficacy, and safety. The studies are initially carried out in experimental laboratories and then proceed to preclinical and clinical trial phases. These studies represent one of the most costly stages of the drug life cycle, both financially and in terms of time. One of the most relevant ways to improve patient access to modern, more effective, and safer medicines is to reduce the cost of pharmacological research without compromising its quality.

Pharmacological studies of potential drugs in laboratory animal experiments play a crucial role in the drug life cycle. At this stage, developers obtain valuable data on the effectiveness and safety of the compounds under investigation, which determines their potential use in humans.

These studies help identify the therapeutic dose, enabling the avoidance of toxic effects and ensuring maximum efficacy.

One of the main reasons for the growing interest in artificial intelligence (AI) is its potential to reduce the cost of drug development. A study published by the Massachusetts Institute of Technology (MIT) showed that only 13.8% of drugs successfully pass clinical trials[25]. The developer should plan to spend an average of 1.3 billion dollars on a new drug to complete the entire clinical trial process and obtain regulatory approval[25].

In drug development, AI assists at the initial stage of screening drug compounds to determine the likelihood of success in bringing them to market, based on pharmacological factors. Next-generation RNA and DNA sequencing technologies help to identify targets faster and individually tailor drugs for specific patients. AI-based systems are also involved in discovering targeted, phenotype-specific drugs, as well as drugs that act on multiple targets simultaneously[26].

AI is used to reduce the likelihood of negative outcomes in preclinical trials. Researchers now use AI to simplify data collection and select subjects for preclinical tests. Data collection and analysis are integral parts of medical research, and it is impossible for a human researcher to track all the available information. However, with the help of AI tools such as deep learning and machine learning, patterns can be analyzed, selected, and relevant data can be linked, potentially leading to the discovery of new drugs. AI can be used to automate the process of preclinical analysis of medical images and drug samples[27].

Artificial Intelligence (AI) technologies have reached a level of maturity that allows them to be used in real-world conditions to assist decision-makers. AI has the potential to transform key stages of clinical trials — from research preparation to execution — which, in turn, increases the success rates of studies and reduces the burden on researchers.

The use of AI allows for the identification of suitable candidates for trials based on medical history, disease status, and additional characteristics such as demographic data and ethnicity, to select the most relevant patient. Real-World Data (RWD) and Real-World Evidence (RWE) play a crucial role in decision-making in healthcare. The use of computers, mobile devices, information-carrying wearables, and other biosensors to collect and store vast amounts of health-related data is rapidly increasing. This data can help pharmaceutical companies better design and conduct clinical studies and medical research to address questions that previously had no solutions. Furthermore, with the development of new complex analytical capabilities, pharmaceutical companies can analyze this data more deeply and apply research findings to the development and registration of medical products [28].

The procedure for preparing a registration dossier involves collecting the necessary administrative documents and summarizing the results of quality, safety, and efficacy studies of the medicinal product. In addition to the previously described capabilities, AI technologies enable intelligent text analysis and automate the presentation of research results. International regulatory bodies have already adopted regulations governing the use of AI in the preparation of analytical research results [29].

Pharmaceutical manufacturing is another area for the implementation of innovative technologies. The "Quality by Design" (QbD) approach is a methodology used to enhance product quality and is characterized by a clearly defined roadmap. Artificial neural networks (ANN) have been successfully used in the development of the tested medicinal product based on QbD to support the establishment of quality control standards for the medicinal product and the limits of controlled parameters in the technological process. This is achieved by linking the development of the drug

formulation with in vitro characteristics, as well as positive clinical outcomes obtained in bioequivalence studies[30]. Continuous pharmaceutical manufacturing is another new approach in the pharmaceutical industry. The level of deviation control allows for adequate process monitoring using deep neural networks (DNN), with critical process parameters being identified at a higher level of understanding of the processes. The synergy between production process analysis and the implementation of AI creates a monitoring system for the continuous production line. The collected data and analysis results ensure the quality of the produced goods[31].

Epidemic forecasting has become one of the most relevant areas of AI application in healthcare in the context of COVID-19. Machine learning (ML) and AI technologies are used for monitoring and predicting outbreaks of epidemics or seasonal diseases worldwide. Forecasting helps plan production capacities and supply chains to ensure necessary stocks are available at the right time and in the required quantities, based on the expected level of morbidity.

The periodic shortage of essential medicines (pharmaceuticals) on the market is a global public health issue. The use of multilayer neural networks for monitoring drug shortages will transition the forecasting process from empirical observations to a scientific forecasting methodology based on modern digital technologies. This involves the analysis, prediction, and modeling of the modern pharmaceutical supply system in its target state [32].

In addition to its application in diagnostics, AI can be useful in clinical practice as a tool for personalizing treatment, supporting decision-making regarding therapy, and managing the concurrent use of multiple medications. Given the importance of analyzing large volumes of data to identify relevant intervention targets and treatment strategies for patients, AI can play a key role in the development of personalized medicines [33]. Machine learning technologies are already being used to predict the treatment outcomes of COVID-19[34].

Automation of the processing of effectiveness and safety justifications for medicines is a significant opportunity to impact one of the most expensive budget items for companies — pharmacovigilance. Expanding access to digital resources and implementing electronic medical records (EMRs) have enabled the use of AI methods for pharmacovigilance. Post-marketing pharmacovigilance is based on various data sources: molecular, chemoinformatic, clinical databases, social media, and biomedical literature. Natural language processing (NLP) methods, based on deep learning, particularly word structure and attention mechanisms, are prioritized for detecting correlations between medicines and adverse reactions (AR) in textual data [35].

The goal of implementing digital systems, particularly those based on AI, is to automate the processes of conducting laboratory studies. Digital systems replace paper protocols [36].

Numerical data and parameters, as well as the content of protocols, are typically transferred into programs like Microsoft Excel, GraphPad Prism, and others for further analysis. However, this process is time-consuming and resource-intensive. The use of primary electronic documentation allows not only to store the original material as evidence of the research conducted, but also to instantly import data into the appropriate programs for parallel analysis. It also creates the possibility of indexing the content of protocols and speeding up the use of the obtained results.

Primary electronic laboratory research protocols solve the problem of creating basic information for deep analysis using neural networks (NN) and machine learning (ML). The application of this methodology by the scientific community in everyday practice will accelerate scientific research and predict their success. This opens up the potential for saving financial resources.

Another direction is the creation of an electronic system for indexing not only the titles of scientific papers but also their content. The foundation of this system will be a specific programming language with a large number of dictionaries and the formation of Big Data with the ability for meta-analysis of scientific research results.

Natural language processing can be divided into categories: quantitative methods based on the simpler "bag of words" principle and more complex methods for understanding natural language. The "bag of words" is a simplified model used in natural language processing and information retrieval. In this model, the text is represented as an unordered set of words, disregarding grammar and even the word order. A simplified assumption is made that these variables are independent. Since these methods mainly rely on word counts as features, there are issues with medical texts because different representations of the same feature are considered as the same characteristic[37]. Natural language processing allows analyzing text and extracting metadata from the content, such as concepts, entities, keywords, categories, sentiment, emotions, relationships, semantic roles, and syntax. It is necessary to create a pipeline for text cleaning, automatic detection and correction of fuzzy words, abbreviations, unit of measurement normalization, date and time format normalization, extraction and defuzzification of text (the process of finding a clear, "crisp" value for each of the output linguistic variables of a set). Several tools are used, including tokenizers[38], Segmenters[39], parse trees, dependency parsers[40]. In the book "Understanding Text from Scratch," Xiang Zhang and Yann LeCun demonstrate that Convolutional Neural Networks (CNNs) can achieve outstanding performance without knowledge of words, phrases, sentences, or any other syntactic or semantic structures of language[41]. In the work by Peilu Wang, Yao Qian, Frank K. Soong, Lei He, and Hai Zhao, part-of-speech (POS) tagging was presented using a recurrent neural network with bidirectional long short-term memory (LSTM) [42].

In the article "Natural Language Generation, Paraphrasing, and User Feedback Summarization Using Recurrent Neural Networks," the authors demonstrate a recurrent neural network (RNN) model capable of generating new sentences and summarizing documents.

Transformers are designed to process sequential data, such as natural language, for tasks like translation and text summarization. Since the Transformer model enables greater parallelization during training, it allows learning from larger datasets than previously possible. This led to the creation of pre-trained systems such as BERT (Bidirectional Encoder Representations from Transformers) and GPT (Generative Pretrained Transformer). These models were trained using vast general linguistic corpora, such as the Wikipedia Corpus, and can be fine-tuned for specific language tasks [43].

Many pre-trained models, such as GPT-2, GPT-3, BERT, XLNet, and RoBERTa, demonstrate the ability of transformers to perform a wide range of NLP tasks and have the potential for practical application in document summarization, text generation, and named entity recognition (NER) [44].

Drug targets are molecular structures whose abnormal activity, associated with a disease, can be altered by a drug, improving the health condition of patients. Machine learning (ML) algorithms commonly used in drug discovery include Random Forest (RF), Naive Bayes (NB), Support Vector Machine (SVM), as well as other methods. Knowledge extraction from large amounts of unstructured data is one of the advantages of these methods[45].

First, artificial intelligence generates millions of potentially new molecules that meet specific specifications. Then, the machine learning platform predicts which compounds will be active

against hundreds of thousands of protein targets. The third level of algorithms, known as active learning, automatically prioritizes which compounds researchers should synthesize and test. These processes allow scientists to accurately design drugs while simultaneously performing a large number of design tasks using AI. Principal Component Analysis (PCA) can be used to reduce the number of parameters of the objects being analyzed. Considering these properties, the molecular representations used in AI-based drug discovery algorithms include: molecular fingerprints, Simplified Molecular Input Line Entry System (SMILES) strings, potential energy measurements (e.g., from ab initio calculations), molecular graphs with varying weights for atoms or bonds, Coulomb matrices, molecular fragments or links, atomic coordinates in 3D, electron density around the molecule, or their combinations. These inputs are used during the training phase of deep neural networks (DNNs) and can be processed by different DNNs at various stages, particularly during the generation and prediction phases. This procedure can facilitate reinforcement learning (RL). In a typical study, the DNN generation phase takes SMILES input data and learns to generate chemically feasible SMILES strings, while the prediction phase learns the properties of the molecules. Although these two phases are initially trained separately using supervised learning algorithms, systematic errors may be introduced when the two phases are trained together—with rewards or penalties applied to certain parameters of each other[46].

For example, the COVID-19 pandemic created a need to assess new chemical and biological entities as potential therapeutic agents against the SARS-CoV-2 infection. The repurposing of previously developed drugs (approved for conditions unrelated to COVID-19) is widely considered as a therapeutic approach against COVID-19. This can involve using intellectual text analysis methods based on dictionaries, in combination with specialized AI or machine learning (ML) techniques such as BioBERT (a bidirectional biomedical language representation model) [47]. A fully connected neural network with direct connections (FNN) is an architecture in which artificial neurons are connected through layers from input objects to output values. The weight is assigned to each connection and is optimized by minimizing the prediction error of output values through backpropagation on training samples. FNN can be used for classifying drugs into pharmaceutical therapeutic classes based on the vectors of the drug's transcriptomic profile[48]. AI-based classification can quickly identify drugs that are capable of fighting new diseases (such as COVID-19) as well as existing ones[49]. For example, a model built on a convolutional neural network (CNN) and a multilayer perceptron (MLP) treats sequences of reference points as one-dimensional images or lines of nucleotide bases, identifying base patterns and potential interactions between them for prediction. Another model, based on natural language processing (NLP), treats each RNA sequence as a "sentence" composed of "word" patterns, and ultimately learns how certain words combine to form meaningful structures [50].

Artificial intelligence algorithms can accelerate clinical trials by automatically identifying suitable participants, ensuring proper group distribution, and creating an early warning system for clinical trials that are unlikely to yield significant results [51]. AI algorithms can be used to verify data accuracy (identifying erroneous entries), completeness (detecting patterns and missing data), systematic errors (data representativeness), and relevance (ensuring data aligns with current clinical practice). Another application of AI in clinical research is based on real-world clinical data (RWD). An AI-based system can recruit patients for a study and perform profiling (e.g., through DNA sequencing, proteomics, metabolomics, etc.). The system then uses RWD to match the studied drugs with the pathologies identified during profiling. Drug-to-patient profile matching strategies in such studies may rely on the analysis of large, relevant datasets using AI and ML.

These algorithms can subsequently be used to support electronic monitoring of research, ensuring data accuracy and patient safety, which reduces the need for expensive on-site monitoring. Additionally, electronic medical record (EMR) data can be combined with other types of RWD, such as genomics and patient complaint reports. This data can be processed using AI and ML methods to create a more comprehensive picture in drug and biomarker discovery [52]. OpenAI has developed a powerful processing model, GPT-3, which is capable of generating human-like text. It is proposed to use GPT-3 in clinical research, for example, to create an FDA-regulated electronic case report form (eCRF) based on a clinical study protocol [53]. The Application Programming Interface (API) for the GPT-3 language model allows users involved in clinical trials to significantly accelerate the development of various applications based on the same technology, such as creating studies or making changes to a protocol.

Artificial intelligence can be trained on a dataset containing images of the effects of pharmaceutical drugs (PDM) on several cell cultures. Alternatively, image classification can be applied in clinical trials for processing medical images. The most common types of image classification algorithms in ML are the K-Nearest Neighbors method, Support Vector Machine (SVM), and Multilayer Perceptrons (MLP). Recently, the most frequently used image classification algorithm is the Convolutional Neural Network (CNN).

CNN is a configured version of neural networks that combines multilayer neural networks with specialized layers capable of automatically extracting the most important and relevant features for classifying an object. CNNs can automatically detect, generate, and learn image features. This significantly reduces the need for manual labeling and image segmentation before feeding them into ML algorithms. They also have an advantage over MLPs because they can work with non-convex loss functions [54].

Personalized medicine, or more effective treatment based on individual health data combined with predictive analytics, is also a prominent area of research and is closely related to the improvement of disease assessment. Currently, this field primarily operates through supervised learning, allowing doctors, for example, to select from a limited list of diagnoses or assess patient risks based on symptoms and genetic information. For instance, the analysis of human DNA sequence data using AI can significantly simplify the process of making a genetic diagnosis of a disease [55]. The development of multifunctional machine learning platforms for extracting, aggregating, managing, and analyzing clinical data can help doctors effectively stratify study subjects, better understand clinical scenarios, and optimize decision-making. The implementation of AI in the healthcare system can significantly improve real-time data delivery, promote more personalized and population-adapted medicine, and reduce costs [56].

Some of the main causes of errors in medical care are related to medication prescriptions: illegible handwriting, incorrect drug selection from an open list, confusion between medications with similar names or packaging, and mistakes in the use of measurement units. Medication errors can be caused by human factors, but often arise from faulty systems with insufficient error detection mechanisms. Big data analytics and machine learning algorithms that analyze electronic medical records (EMR) data can be used to study how doctors treat patients in real-world conditions. AI technologies can check the correctness of medication prescriptions during dispensing and administration [57].

ML and AI technologies are also used for monitoring and predicting epidemic outbreaks worldwide based on data collected from satellites, historical information on the internet, real-time social media updates, and other sources. Support vector machines and artificial neural networks

have been used, for example, to predict malaria outbreaks by considering data such as temperature, average monthly rainfall, total confirmed cases, and more [58].

Digital systems for medical and pharmacological purposes must not only ensure the ability to register but also facilitate further processing using complex mathematical formulas and medical statistics. In healthcare, the "1C" program is widely used, which, however, is mostly limited to accounting tasks.

The implementation of deep learning methods (a combination of supervised, semi-supervised, unsupervised, and reinforcement learning techniques based on learning representations rather than specialized algorithms for specific tasks), using various classification and clustering methods, will help improve the capabilities of preclinical research in finding the appropriate combination of drugs for treating a wide variety of human pathologies. This technology can also become an auxiliary tool for further studying the effects of drugs on the body and identifying new targets for their action.

The Impact of Artificial Intelligence on Personal Rights in Pharmacy

The use of artificial intelligence (AI) in healthcare comes with several challenges and limitations. First and foremost, this concerns access to patients' personal and confidential data, potential biases in such data, the risk of incorrect diagnoses, as well as technical errors in the functioning of AI.

The introduction of AI creates significant challenges for ensuring an individual's right to privacy, which requires strengthening legal guarantees for the protection of personal information.

In this context, it is worth paying attention to legal regulation in the European Union, particularly regarding the processing of personal data in the pharmacy sector using AI.

The right to privacy is enshrined in both universal and regional international agreements. In particular, according to Article 12 of the Universal Declaration of Human Rights, no one shall be subject to arbitrary interference with their privacy, family, home, correspondence, or to attacks upon their honor and reputation. Everyone has the right to protection from such interference or attacks under the law [59].

The International Covenant on Civil and Political Rights (Article 17) establishes: "1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home, or correspondence, nor to unlawful attacks on his honor and reputation. 2. Everyone has the right to protection from such interference or attacks according to the law" [60].

The European Convention on Human Rights (ECHR) of 1950, in Article 8, defines the right to privacy as follows: "1. Everyone has the right to respect for his private and family life, his home, and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society for national security, public safety, the economic well-being of the country, the prevention of disorder or crime, the protection of health or morals, or for the protection of the rights and freedoms of others"[61].

The Charter of Fundamental Rights of the European Union of 2000, in Article 7, proclaims a similar right to respect for private and family life, the inviolability of the home, and the secrecy of communications, which aligns with the provisions of Article 8 of the European Convention on Human Rights (ECHR). An important innovation of the Charter is Article 8, which specifically protects personal data, confirming that the basis of the right to privacy is the collection and processing of information about an individual [62].

On December 2, 2020, the Concept for the Development of Artificial Intelligence was approved, outlining the main directions for the development of this field, with the priority task being the development of a national Ethical Code for Artificial Intelligence [63].

One of the first regulatory documents of the EU aimed at addressing issues related to artificial intelligence was the AI Act. Initiated by the European Commission on April 21, 2021, it envisages the creation of a unified approach to regulating AI, taking into account the level of risk posed by each technology. The Act defines the obligations for AI developers and users.

On June 7, 2022, the Steering Committee on Bioethics and Health (CDBIO) of the Council of Europe published a report addressing the use of AI systems from the perspective of human rights principles. The analysis was based on the provisions of the Convention on Human Rights and Biomedicine of 1997, more commonly known as the Oviedo Convention. The document specifically highlighted the potential impact of AI on the implementation of human rights, with a particular focus on the right to respect for private life in the context of processing sensitive health data [64].

According to the aforementioned report, one of the important and unique issues related to the use of artificial intelligence is the use of patients' personal data for training and validating such systems. Confidentiality in the relationship between doctors and patients is a fundamental element of protecting the right to privacy. However, the rapid development and integration of AI in the pharmaceutical field is accompanied by an increasing need to form or access large volumes of real medical data from patients to ensure the effective functioning of the relevant algorithms.

Innovations in the pharmaceutical sector may pose a threat to the privacy and confidentiality of patients in two main aspects:

First, the risk increases regarding the reuse or transfer of so-called "anonymized" patient data, including electronic medical records, to third parties for the purpose of testing or developing AI systems.

Second, healthcare professionals may be incentivized to prescribe additional tests not for their diagnostic or therapeutic necessity but solely due to their potential value for training or improving AI algorithms. This approach has consequences in terms of increasing the financial burden on the healthcare system and raising the risk for patients due to potential privacy violations or leaks of personal information.

The Oviedo Convention clearly defines the application of the right to respect for private life, guaranteed by Article 8 of the European Convention on Human Rights (ECHR), emphasizing the particular sensitivity of medical information. It imposes an obligation on healthcare professionals to strictly adhere to confidentiality. Therefore, the collection and use of data that does not have direct clinical necessity but is solely intended for the testing of AI may be considered a violation of the right to privacy enshrined in the ECHR.

Thus, even in the presence of a justified need to use real medical data for training and testing AI systems, the pursuit of innovation and the improvement of medical services must be accompanied by respect for patients' rights to privacy and confidentiality. A violation of this balance could undermine patient trust in the healthcare system, as it would indicate the failure of institutional protection of patients' personal interests.

At the very least, the use of patients' medical information for the purpose of training and improving AI systems should be conducted using reliable de-identification methods and ensuring a higher level of data confidentiality.

Another key regulatory document in the field of personal data protection in the medical context is the Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CETS No. 223), which came into force after ratification in October 2023. This Protocol updates the provisions of the foundational Convention (ETS No. 108), and is particularly important for the application of artificial intelligence in medicine. It revises Article 8 (now Article 9), which enshrines an expanded list of rights for individuals concerning the protection of personal data.

According to the updated provisions, every individual has the right to:

- Not to be subject to a decision that significantly affects them if such a decision is made solely by automated means, without the possibility of considering their point of view;
- receive, upon request, within reasonable time and without excessive delays or costs, confirmation of whether their personal data is being processed, accessible and understandable information about the content of the processed data, the source of its origin, storage periods, and other relevant information;
- know the grounds on which the data is processed if its results relate to a specific individual;
- object to the processing of personal data if there are no legitimate grounds for such processing;
- apply legal protection mechanisms if their rights, guaranteed by the Convention, have been violated.

Many of the rights mentioned reflect the protections provided by the General Data Protection Regulation (GDPR) — the foundational legal act of the European Union, which came into force in 2018. These include, in particular, the limited right not to be subject to automated decision-making, the right to receive detailed information about the processing of personal data, and the right to request the correction or deletion of such data.

To address issues related to the use of artificial intelligence, on March 13, 2024, the European Parliament adopted the world's first regulatory act dedicated specifically to AI — the AI Act. The main objective of this law is to ensure the protection of fundamental rights and freedoms of individuals who may be affected by artificial intelligence technologies. The document establishes key principles and rules regarding the processing of personal data, the functioning of automated decision-making systems, and other AI components, with a focus on transparency, legality, and non-discrimination in such processes. Particular attention is given to the protection of privacy and personal information, notably through a ban on the use of biometric classification and emotion recognition systems. In addition, the Act guarantees citizens the ability to file complaints concerning the operation of AI systems and to receive reasoned explanations for decisions that affect their rights.

It is important to emphasize that a significant portion of artificial intelligence technologies, particularly in the pharmaceutical field, eventually falls under the control of private companies. The specifics of AI implementation may lead to private corporations, medical institutions, and government agencies gaining expanded access to patients' health data, raising serious concerns about privacy and the security of personal information [65].

Since AI technologies are often characterized by a lack of transparency in their functioning, effective oversight will require active engagement with the companies that develop and own these solutions. The concentration of technological capabilities and expertise in the hands of large IT companies may shift the balance of power, causing public authorities to lose parity in partnerships and become dependent on the private sector in implementing digital solutions in the medical field.

This also increases the risk of unauthorized sharing or transfer of personal medical data between such companies.

One of the key challenges in protecting personal data when using artificial intelligence in medicine is the risk of automated decision-making that can have legal consequences for individuals. In a medical context, AI is capable of making decisions that significantly affect the rights and freedoms of patients.

For example, when making a diagnosis, a system may conclude that an individual does not meet certain requirements to perform professional duties due to their health condition. In such cases, to comply with data protection legislation, it is crucial that data subjects have access to complete information regarding the processing of their data and are able to understand the logic on which the system based its decision.

The transparency of algorithms must be ensured to such an extent that individuals affected by automated decisions can understand their basis and defend their legitimate interests. Therefore, AI algorithms intended for use in medical practice must incorporate explainability mechanisms that make the decision-making process more understandable, transparent, and accountable.

Given the scale of medical data processing by artificial intelligence, there is a need to establish unified technical and organizational standards to regulate these processes. This may include the introduction of uniform requirements for specific types of data processing, which would contribute to the effective protection of personal information in the healthcare sector.

This can be achieved by creating a specialized certification body that would oversee AI systems intended for medical use. Such an institution would develop and implement the necessary security measures which, in accordance with the provisions of the GDPR, would ensure the reliable protection of personal medical data and control over access to them.

Conclusions

To accelerate the industrialization of the pharmaceutical sector through cross-cutting technologies and to promote the use of artificial intelligence for improving the organization of pharmaceutical activities, it is necessary to:

− Develop unified technical regulations to ensure high product quality, reduce the number of inspections of production facilities, and support pharmaceutical organizations (manufacturers) in effectively managing increasingly complex supply chains;

− integrate into the production and commercial practices of pharmaceutical organizations the principles used in software development, with a strong focus on data analysis and management to create added value for the pharmaceutical industry as a business sector;

− address the shortage of qualified specialists, especially for enterprises collaborating with research organizations at interregional, international, and supranational levels within their strategies for developing scientific competencies;

− align regulatory requirements with current realities to enable the implementation of information, digital, and smart technologies as well as pre-certification procedures;

− amplement cloud systems and platform-based solutions within pharmaceutical organizations to enable interaction and compatibility with regulatory authorities' databases;

− digitalize supply chains using artificial intelligence; machine learning and additive manufacturing technologies can be used in digital supply networks to transmit, record, and analyze data.

− apply a comprehensive approach to the innovation of pharmaceutical organizations, for example, through the integration of blockchain technologies, which enable secure data

implementation and achieve breakthrough results in ensuring data privacy and security both within and beyond the organization;

− develop a resilient system architecture and transparent interaction framework for all participants in the pharmaceutical ecosystem. This will allow for the engagement of end-users in the value creation process, improve reimbursement procedures, accelerate product development and market entry, and reduce research and development costs.

At the same time, the use of artificial intelligence in the pharmaceutical sector can save lives but also introduces new risks and challenges related to the violation of human rights. Therefore, it is essential to develop and implement effective legal regulation of AI systems at the international level.

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