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Problems of Receiving Services in the Digitalization Mode in the Field of Medicine Circulation

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ABSTRACT. This scientific article is devoted to the urgent problems of obtaining services in the digitalization mode in the field of medicines circulation. The main directions of the digitalization process implementation in the field of circulation of medicines in Ukraine are disclosed, attention is focused on the positive and negative aspects of digitalization in the field of circulation of medicines in Ukraine. Possible directions for improving digitalization in the field of medicines circulation in Ukraine are identified, and attention is focused on the need to improve the legal regulation of digitalization in the field of medicines circulation in Ukraine in order to protect the rights and interests of services recipients in the field of medicines circulation.
***Keywords**: digitalization, pharmaceuticals, legal regulation, legal liability, pharmaceutical services*

1. INTRODUCTION

Digitalization for Ukraine is a new concept and direction of the work of public administration entities. There is still no normatively defined concept of digitalization in the legal field, which makes it possible to broadly and ambiguously interpret this concept, highlight areas and forms of activity, as well as avoid legal liability for misinterpretation in the process of resolving legal relations arising between legal entities in the implementation of their right, but in digital mode. That is why, our task is to conduct a broader study of the issue of receiving services in the digitalization mode in the field of medicines circulation, as well as identifying the shortcomings of this process and suggesting possible ways to improve it.

1.1. Related Work

The problems of digitalization in the field of law were dealt with by O. Kibenko, who noted that digitalization provides for changes in the procedures regulated by law and related to the transition from paper-based processes, in which applicant's personal presence in front of the competent authority is mandatory, to direct online procedures, not requiring the direct involvement of an intermediary or competent authority (end-to-end direct online procedure) [2]. M. Prokhorov notes that digitalization in the field of law is a word chosen rather for hype. This should actually be called digital transformation [9]. David Brown, I. Smelyanskyi, N. Kovalyova, S. Pogrebna, A. Ivasiv, note that digitalization is an inevitable process that becomes relevant in both public and private law. Digitalization makes it possible to improve and speed up work, as well as increase productivity [10].

1.2. Our Contribution

Based on the study of the problem of receiving services in the digitalization mode in the field of medicines circulation, we focused on the need to implement an integrated electronic document management system to support the medicines life cycle, that is, the possibility of creating and introducing such a digital portal where you could trace the entire production path, packaging, dispensing, logistics and acquisition of a medicinal product, enhancing the legislative work of lawmakers to introduce electronic dossier of medicines and digititalization of all processes associated with the medical and clinical research. Actions on the part of state bodies are also needed for serialization - labelling of pharmaceutical products with the aim of monitoring them; special attention is required to bringing to legal responsibility in the context of digitalization in the field of circulation of medicines. So, today, it is advisable for the legislator to improve the norms of the current legislation to prevent the circulation of counterfeit medicines in order to ensure consumers' rights to safe and highly effective medicines. The solution to this issue seems possible by making appropriate changes and additions to the Code of Ukraine on Administrative Offenses and the Criminal Code of Ukraine.

1.3. Paper Structure

In the first part of the article, the foundations of the formation and development of digitalization in Ukraine in the field of medicines circulation are investigated and disclosed. In the next part of the work, based on the analysis of the results of digitalization achievements in Ukraine in the field of medicines, attention is focused on the existing shortcomings of this process and ways to improve this process are proposed.

2. BACKGROUND

The field of drug trafficking is now playing an important social role, providing people with medicines, which is one of the key elements of Ukraine's public and national security, as the availability of quality and safe medicines, the introduction of innovative medicines for treatment is an important prerequisite for ensuring the health and life of the Ukrainian population. . The International Organization for Economic Co-operation and Development (OECD) notes that in the European countries in 2010–2018, the use of innovative medicines has stimulated progress in the treatment of diseases and prolonged life expectancy by 73% [17; 18].

An important step towards Ukraine's European integration with the World Community is its accession to the World Trade Organization and the signing of an Agreement with the European Union, which requires the state to strike a balance between the interests of drug manufacturers and their consumers (patients). At present, the overriding problem of the pharmaceutical field is the low quality and high cost of domestic medicines, which depend on the health of the nation and the life expectancy of the people. Therefore, public administration of this area is urgent, since it is the implementation and adherence to European standards in the circulation of medicines in the form of international directives, guidelines and norms that will make it possible to bring to the European level the quality of medicines, their safety and accessibility for patients [17].

Today, there are a large number of dangerous, counterfeit, substandard drugs containing toxic substances, substandard active pharmaceutical ingredients in the domestic pharmaceutical market, which do not have a curative or prophylactic effect, but lead to irreparable consequences in the human body, cause infectious diseases and cause infectious diseases. diseases.

In Ukraine, the issue of digitalization has been actively developed since 2019. However, the absence of a specially created authority did not make it possible to expand the legal field for the implementation of the concept of digitalization and, accordingly, the implementation of certain trends. That is why it was timely and necessary to create on September 18, 2019 in the structure of the executive authorities of Ukraine a central executive authority, the activities of which are directed and coordinated by the Cabinet of Ministers of Ukraine of the Ministry of Digital Transformation of Ukraine (Digital Ministry). This body has become the main body in the system of central executive bodies, ensuring the formation and implementation of state policy in several directions at once: in the areas of digitalization, digital development, digital economy, digital innovation, e-government and e-democracy, the development of the information society, informatization; in the development of digital skills and digital rights of citizens; in the areas of open data, the development of national electronic information resources and interoperability, the development of the infrastructure of broadband Internet access and telecommunications, electronic commerce and business; in the provision of electronic and administrative services; in the areas of electronic trust services of electronic identification; in the IT industry development. The Digital Ministry provides the functions of a central certifying authority [1].

Thus, digitalization in the law provides for reformatting and introducing qualitatively new changes in the procedures regulated by national legislation and related to the transition from paper-based processes in which personal presence of applicants in front of the competent authority is mandatory, to direct online procedures that do not require direct participation of an intermediary or competent authority (end-to-end direct online procedure). Digitalization is replacing old communications such as electronic communications, telephone, fax, telegraph. New digital technologies allow you to create and distribute huge amounts of information for an almost unlimited circle of people quickly, efficiently, without any significant cost. At the same time, emphasis is placed on three basic elements: on-line procedure, that can be carried out through the web network and is available to end users of services; direct on-line procedure, which can be carried out directly by the end user independently, that is, without the intervention of an intermediary or a competent authority; continuous on-line procedure (end-to-end), all stages or actions of which occur exclusively online, not a single element does not require the use of paper media or physical presence [2].

Given the new capabilities of digital administration, a logical question arises: how can we improve the process of communication and legal regulation of legal relations in the field of medicines circulation? At the same time, without violating, but protecting the rights of the subjects of such legal relations, to unify the activities of the executive authorities and reduce the time to receive certain types of services? In the context of these issues requiring a high-quality update, the approaches to the disclosure of information, protection of information and methods of their transmission were legislatively defined, in fact almost all the norms of national legislation (for example, the laws of Ukraine "On Information" (1992), "On Medicines" (1996), "On electronic documents and electronic document management" (2003), "On public procurement (2015), etc.) were adopted much earlier than the introduction of digitalization in the legal sphere started.

In order to receive services in the digitalization mode in the field of medicines circulation in Ukraine, state registers of medicines have been created. The state register of medicines in Ukraine is being created with the aim of providing state authorities with reliable information about

the state of existence of objects in the public administration system. The state register is maintained on electronic media in accordance with state standards that ensure its compatibility and interaction with other information systems and networks that make up the state's information resource. Information constituting a state secret is not entered in the state register. It is maintained by the competent authority in electronic form using the material and technical base of the territorial bodies of the competent authority in the established form [3].

The pharmaceutical encyclopedia defines "medicinal product" as a product of pharmaceutical activity having a certain composition, a specific dosage form, packaging, shelf life [11]. It is prescribed to a sick person for the purpose of diagnosis, treatment or alleviation of symptoms of the disease or changes in the state of physiological functions of the body, as well as prevention, for example, contraceptives, stress drugs and the like. Strict requirements (therapeutic efficacy, safety, accuracy of dosing of active substances, stability, etc.) are imposed on medicines, and they are allowed to be used in medical practice only after state registration [11].

Pharmacologists suggest a more formal definition of the drug. I.S. Chekman believes that a "medicinal product" is a pharmacological agent of natural, synthetic or semi-synthetic origin, which has the property of preventing the occurrence of a pathological process or causing a therapeutic effect in diseases and is officially authorized for use in the treatment of patients by an official body of the state [12, p. 31].

M.I. Yablulyanskiy and V.M. Savchenko by "medicinal product" means a pharmacological agent authorized in an established manner by an authorized body for use in treating, preventing or diagnosing pathological conditions (diseases and clinical syndromes) in medical and veterinary practice [13, p. 7].

G.R. Dzonov, N.I. Makhonko the term "drugs" refers to substances used for the prevention, diagnosis, treatment of diseases, prevention of pregnancy, obtaining plasma from the blood, as well as organs, tissues of humans or animals, plants, minerals by methods synthesis or with the use of biological technologies [14].

The circulation of medicines must guarantee their quality, safety and efficacy, which in turn is a guarantee of the health of every nation. Medicines should be potentially safe for patients. The pharmacological encyclopedia of drug treats the term as a form of activity that shapes the integrity of the reproduction spheres: direct production, exchange, distribution and consumption, that is, activities related to the creation, production (manufacture), storage, transportation, import to Ukraine and export from Ukraine, sale, use, disposal or disposal of medicines [11]. O.V Pasichnyk by "drug circulation" means the legal relations arising from the beginning of the creation of a chemical formula of a future medicinal product through production until its receipt by the consumer in the form of finished pharmaceutical products [15, p. 5]. V.M. Pashkov defines "drug medicines" as a specific type of legal relationship that requires the benefits of organizational, compulsory measures that come from state and public interests. The author notes that in the legal aspect, the issue of ensuring the circulation of medicines can be divided into three components: registration of medicines, production or importation, implementation [16]. Secondly, the author defines turnover as a specific type of legal relationship ..., which includes registration, which, we believe, acts as a permissive act of public administration in the field of medicines circulation. G.R. Dzonov, N.I. Makhonko believe that "drug medicines" is a generic concept of activity, including development, research, production, manufacturing, storage, packaging, transportation, state registration, standardization and quality control, sale , marking, advertising, use of medicinal products, destruction of unusable medicinal products or expired medicinal products and other activities in the field of circulation of medicinal products [14].

Therefore, it is expedient to formulate the "circulation of medicinal products" of its own definition of the specified category as a form of pharmaceutical activity, which consists in the creation, production, storage, transportation, quality control, import, export, sale and disposal of medicinal products. Accordingly, the features of the term "drug circulation" are: a variety of pharmaceutical activities; presence of stages of circulation of medicines, which are: creation of medicines; production of medicines; storage of medicines; import and export of medicines; sale of medicines; disposal of medicines [17].

Thus, the circulation of medicines is a type of pharmaceutical activity that is carried out within the healthcare sector as a "specialized" and large-scale specialized activity. Therefore, there is a need to create a separate legal institute within which these activities will be regulated, namely the institute of medical law with its related elements. Since today medical law is a branch of law and part of legal science, which becomes relevant in the light of the reforms and going through an important time for yourself as an institution of law [17].

It should be noted that medicines can not be used in Ukraine unless they have been registered. The only exceptions are medicines that are manufactured in pharmacies by prescriptions and at the request of medical establishments with authorized active and auxiliary substances that are not subject to state registration. Accordingly, the registration of medicinal products is a procedure that is carried out in accordance with the requirements of the current legislation in order to grant or extend the authorization for medical use of medicinal products. Art. 9 of the Law of Ukraine "On Medicines" stipulates that medicines are allowed to be used in Ukraine immediately after their state registration. In order to characterize the registration procedure itself, it is advisable

to propose its own determinant "registration of medicinal products", which, in our view, should be represented by two concepts: the first concept will define "registration of medicinal products" as a means of public administration in the field of circulation of medicinal products, by which medicinal products obtain official recognition; According to the second concept, “registration of medicinal products” is an order of action exercised by authorized public administration entities in the field of circulation of medicinal products by performing registration activities by entering general information about a medicinal product in the Unified State Register, which results in recognition of the legitimacy of medicinal products. the means and issuance of the relevant official certificate of direct state registration of the medicinal product. The state registration of medicinal products is carried out by means of a registration procedure, which is assigned to complicated, non-conflict administrative administrative proceedings. Registration proceedings cover a wide range of public relations and occupy a special place in the structure of the administrative process. It should be noted that during the registration procedures in the activity of public administration bodies and their officials, the legality of the respective object of registration is officially recognized. It encompasses a large number of public administration entities and their officials - from "registrars" and individuals and legal entities who apply to a public administration entity to pursue the public interest, ie "registrants". During the registration procedure, the relevant acts, events, actions, property rights, place of residence, recognition of the status of foreigner and stateless person, objects, objects and regulations are registered. For the import and sale of medicinal products on the territory of Ukraine, it is necessary to carry out their state registration, as well as to fulfill the necessary requirements regarding their quality [17].

Medicines manufactured at pharmacies by prescriptions (backbone formulas) and on the order of treatment-and-prophylactic establishments (official formulas) of authorized active and auxiliary substances are not subject to state registration.

A drug cannot be recommended for state registration unless the results of the specialized examination confirm the conclusions on its effectiveness, safety and quality,

namely, a medicinal product harmful to human health (outweighing the risk of using the medicinal product over its expected benefit); the composition of the medicinal product does not correspond to that specified in the registration materials; registration materials do not meet the established requirements; if the court decision has come into force that such registration will infringe intellectual property rights protected by the patent of Ukraine, including in the production, use, sale of medicines, etc. [17].

The State Register of Medicines contains information on medicinal products authorized for production and use in Ukraine. The register is maintained in order to ensure: the identification of business entities engaged in the manufacture and sale of medicinal products on a professional basis, in compliance with relevant standards and rules in this field; organization of statistical observations in the field of medicines circulation; interaction on unified methodological bases with databases of other central executive bodies; publicity and openness of information about business entities; identification of the drugs being purchased.

Thus, according to the results of registration activities in the field of drug trafficking, the central executive body that directly forms and ensures the implementation of state policy in the field of drug trafficking (State Expert Center, State Service for Medicinal Products and Drug Control) and the central executive authority , which shapes and ensures the implementation of state policy in general in the field of health (Ministry of Health of Ukraine), forms and provides: a) spare re examination and registration of drugs; b) keeping state registers of medicines; c) providing information from the registers to interested parties [17].

The state register of medicines contains information about:

- medicines approved for production and use in Ukraine;
- identification of business entities engaged in the production and sale of medicines on a professional basis in compliance with relevant standards and rules in this area;
- organization of statistical observations in the field of medicines circulation and the results of such statistical indicators in various directions;
- interaction on uniform methodological principles with databases of other central executive bodies;
- list and brief description of purchased medicines.

So, according to the results of registration activities in the field of medicines circulation, the central executive authority, which directly forms and ensures the implementation of the state policy in the field of medicines circulation (State Expert Centre, State Service for Medicines and Drug Control) and the central executive authority, which forms and ensures the implementation of state policy in general in the field of healthcare (Ministry of Health Of Ukraine), form and provide: a) the procedure for the examination and registration / re-registration of medicines; b) maintaining state registers of medicines; c) providing information from the registers to interested parties.

It should be noted that on the official website of the State Expert Center of the Ministry of Health of Ukraine in the section "State Register of Medicinal Products of Ukraine" today there are the following registries: 1. The State Register of Homeopathic Medicines, which includes 10531 medicines, of which 3541 ones are of domestic origin, 6990 ones are of foreign origin; 2. The State Register of Active Pharmaceutical Ingredients (Substances), which includes 2080 units, of which: of domestic origin – 329 ones, of foreign origin – 1751 ones; 3. The State Register of Medicines “in bulk” (without

packaging and / or final packaging and labelling), which includes 629 medicines, of which 210 ones are of domestic origin and 419 ones are of foreign origin; 4. The state register of medicines with packaging in bulk.

Thus, as of January 26, 2020, the State Registers contain 13,426 medicines, of which 4,136 ones are of domestic origin and 9,290 ones are of foreign origin [4].

By introducing digitalization in the field of medicines circulation, medicines suppliers have a new opportunity for electronic communication with the Ministry of Health of Ukraine and the State Expert Centre of the Ministry of Health through the creation of a program module for the applicant's personal electronic office, in which the customer (an entity representing medicines on the Ukrainian market) can send reports to the State Expert Centre of the Ministry of Health on adverse reactions of medicines, including vaccines / tuberculin, represented on the Ukrainian market, thus realizing their right to receive high-quality medicines and protecting their rights from their violation, including negative pharmacological effect on customers health. The customer's electronic account provides an algorithm of the customer's actions in the event of receiving low-quality medicines, as well as the procedure for providing access to APIS (automated pharmacovigilance information system) through ECO created by the Applicant.

The main condition for using this functionality is the signing of an agreement between the Customer (Applicant) and the Contractor (State Enterprise "State Expert Centre of the Ministry of Health of Ukraine").

The services contract provides for the provision of services to the Customer and the conditions for terminating the provision of services with paid access to a database of adverse reactions and / or lack of effectiveness in the medical use of medicines, including vaccines / tuberculin, represented on the Ukrainian market, in an automated Information pharmacovigilance system through an electronic office already created by the Customer, within 1 year from the date of activation of Customer access to the APIS database.

The use of these services is entitled to the authorized person responsible for pharmacovigilance / contact person (hereinafter - APRP / CPRP), appointed by the Applicant [6].

However, the presence of this software does not allow the communication of consumers of medicines with the relevant authorities and suppliers of medicines in assessing their effectiveness or the presence of adverse reactions. In our opinion, the solution of this issue is possible by introducing online communication through the creation of the tab "Electronic book of reviews of medicines" on the website of the Ministry of Health of Ukraine, and it is necessary to provide for the responsibility of the Ministry of Health of Ukraine for failure to verify the electronic application-response and control the provision of a thorough written response to the legal address previously indicated by the consumer of medicines in compliance with the Law of Ukraine "On the appeal of citizens."

One of the effective steps of digitalization in the field of medicines circulation is the ability to carry out an online order of the corresponding medicines. The positive aspects are: firstly, there is a frequent discount on most types of medicines; secondly, the ability to instantly find out about the presence or absence of the necessary medicinal product, thirdly, the provision of information on the qualitative and quantitative indicators of the medicinal product and the actual address of the pharmacy where the medicines can be purchased; fourthly, if it is impossible, for physiological reasons, for a person to independently carry out an online order of a medicine, a pharmacy kiosk employee will help to carry out an online order, and the person will also be able to create an online order and receive benefits on a common basis.

Another positive innovation in the context of the introduction of digitalization in the field of medicines circulation is the design of an online patient prescription. The subject of the online prescription is all primary care doctors working in medical institutions partnering with the National Health Association: communal, private, and GP doctors.

Due to the transition of the Affordable Medicines reimbursement program to the NHAU, patients will be able to refill their prescriptions at any pharmacy in Ukraine that takes part in the program. This will expand the ability of primary care physicians to prescribe medications for all patients who have signed declarations with them. This applies to all primary care physicians working in partner institutions of the National Health Association: communal, private, and GP-doctors. Doctors fill out prescriptions for the program in the electronic healthcare system using the medical information system, which is installed in the medical facility. For this, it must have an appropriate module. Now, according to electronic recipes, medicines are available under the Affordable Medicines program. They can be written by a primary care doctor, a family doctor, therapist, paediatrician for the patient who signed the declaration with him. During the patient's visit, the doctor opens the patient's card in his medical information system and begins or continues the medical episode. The National Health Association is in touch with 436 pharmacies. These are approximately 6,600 points of sale throughout the country. When they conclude an agreement with the NHAU, patients will be able to get medicines in the "Affordable Medicines" program at these pharmacies for free or with a small surcharge [7].

In order to control the implementation of the Affordable Medicines program, another digital resource Trembita has been created in Ukraine. "Trembita" allows you to build secure informational interagency interactions between government bodies and local governments through the exchange of electronic messages between their information systems. The first automatic data exchange through Trembita was made between the National Health Association of Ukraine and the State Service for Medicines and Drug Control. Thanks to this information exchange, more than one million automatic data checks are carried out every month during the implementation of the Affordable Medicines program. Such a system allows a simplified check of pharmacies for a license three times - during registration and conclusion of an agreement

between pharmacies and the NHAU, realization of electronic prescriptions in pharmacies and the presentation by pharmacies of NHAU reports on dispensed medicines, on the basis of which their cost is refunded. “Trembita” allows reimbursing from the state budget the cost of medicines under the “Affordable Medicines” program to those pharmacies that operate legally under this program [8].

3. CONCLUSION

The presence of the indicated positive steps in the digitalization process that have been launched in the field of medicines circulation in Ukraine testifies to the active position of the legislator regarding the legal regulation of this issue, as well as the decisive and effective steps of state authorities and local authorities on their implementation. However, despite the positive trends, still many issues remain unresolved. In particular, attention should be paid to the introduction of an integrated electronic document management system to support the life cycle of medicines, that is, the possibility of creating and introducing such a digital portal where you could trace the entire path of production, packaging, dispensing, logistics and the purchase of medicines.

On the example of the countries of the European Union, it seems possible and necessary to intensify the legislative activity of the legislator on the introduction of an electronic dossier of medicines and the digitalization of all the processes related to medical and clinical research. Actions on the part of state bodies are also needed for serial production - labelling of pharmaceutical products with the aim of monitoring them.

Particular attention is required to the problem of bringing to legal responsibility in the context of digitalization in the field of circulation of medicines. So, today, it is advisable for the legislators to improve the norms of the current legislation to prevent the circulation of counterfeit medicines in order to ensure consumers' rights to safe and highly effective medicines. The solution to this issue seems possible by making appropriate changes and additions to the Code of Ukraine on Administrative Offenses and the Criminal Code of Ukraine.

The actual issue of the development of the digitalization process in the field of medicines circulation in Ukraine remains the material and technical support of this process. So, it should be noted that a significant part of the territory of Ukraine does not have a proper Internet connection. This circumstance makes it difficult or even impossible to digitalize throughout Ukraine, and the territorial criterion is the basic one, because digitalization should be available in every small village in Ukraine. Only then can we talk about the successful implementation of the digitalization reform in the field of medicines circulation in Ukraine.

Also, while implementing the digitalization reform in Ukraine, it is still worth emphasizing the need for an archive storage for the processed information, where it will be stored and accumulated in the process of electronic reformatting.

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