

UDC 340.134:004.738.5:339.37:615.2 (477)

DOI: 10.15587/2519-4852.2021.201074

RESEARCH OF APPROACHES TO FORMATION OF LEGISLATION IN THE SPHERE OF ONLINE RETAIL SELLING (DISTANCE SELLING) OF MEDICINES

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The aim of the study is to study approaches to the formation of legislation in the field of the online retail selling (distance selling) of medicines in the EU with further development of areas for improvement of pharmaceutical legislation of Ukraine.

Materials and methods. During the research, scientific methods were used, in particular, system-analytical, content analysis, comparative legal, graphic, etc.

Results. The main provisions of the EU Directives 2000/31/EU “On some legal aspects of information services, in particular, electronic commerce, in the internal market” (Directive on electronic commerce) and EU Directive 2001/83 EU “On the Community code relating to medicinal products for human use”, the Council of Europe Convention “On counterfeiting medical products and similar involving threats to public health”, Implementing Regulation of the EU Commission No. 699/2014 of June 24, 2014, as well as the Law of Ukraine “On Electronic Commerce”, “On Medicines”, Resolution of the Cabinet of Ministers of Ukraine (CMU) of March 23, 2020 No. 220, of November 30, 2016 No. 929 and others.

Conclusions. The main directions of improving the current legislation of Ukraine in the field of the online retail selling of medicines are proposed. The necessity to supplement the Regulation “On the State Service of Ukraine for Medicines and Drug Control” (Resolution of the Cabinet of Ministers of Ukraine of November 30, 2016 No. 929) with certain norms has been substantiated. In particular, to impose on this state body the obligation to register business entities that plan to sell drugs using information and communication means, as well as maintain their Register

Keywords: medicines, e-retail, information and communication facilities, licensing conditions, pharmaceutical legislation, regulations

How to cite:

Volkova, A., Boldar, G., Ryshchenko, O., Proskurova, Ia. (2021). Research of approaches to formation of legislation in the sphere of online retail selling (distance selling) of medicines. ScienceRise: Pharmaceutical Science, 5 (33), 64–70. doi: <http://doi.org/10.15587/2519-4852.2021.201074>

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1. Introduction

After signing and ratifying the Association Agreement between Ukraine and the European Union (EU), our state has undertaken a number of legal obligations, in particular, to ensure the gradual adaptation of national legislation to EU law in accordance with the areas defined in the Agreement, one of which is electronic commerce [1, 2]. An important step aimed at fulfilling this task was the adoption on September 17, 2020 of the Law of Ukraine “On Amendments to Article 19 of the Law of Ukraine “On Medicines” (Law 4 904-IX), which enshrines the possibility of pharmacy retail trade in medicines (drugs) through information and communication networks [3].

In the EU, the procedure for conducting selling medicines online (distance selling) to the public is regulated by special regulations, the legal norms of which ensure the acquisition of positive practical experience in carrying out such activities in European countries. According to research in Ukraine, for the effective implementation of the mechanism of the online retail selling of medicines, it is necessary to further develop and adopt a number of regulations [4–6].

The urgent need to create a proper system of legal regulation of pharmaceutical care to the population of Ukraine in terms of the introduction of online retail selling of medicines is due to a number of reasons, including: the spread of self-medication among the population; detection of errors related to drugs, in particular during retail selling in pharmacies [7]; formation of new market conditions of competition among pharmacies and their networks, as well as the introduction of new marketing approaches to the formation of the product range of pharmacies and attracting consumers [8].

The aim of the study is to study approaches to the formation of legislation in the field of the online retail selling (distance selling) of medicines in the EU with further development of areas for improvement of pharmaceutical legislation of Ukraine.

2. Planning (methodology) of research

The study consisted of several stages. At the first stage, regulations and scientific literature on the topic were studied, the directions of research were chosen. In particular, on the basis of elaboration of sources of law in the field of retail selling medicines online (distance), the

main requirements to business entities carrying out this type of activity in accordance with the legislation of the EU and Ukraine were determined. The inconsistency of the Ukrainian legislation with the requirements of the EU directives on the existence of a state supervisory body as a participant in the implementation of online retail selling of medicines has been revealed. In addition, the expert opinion of domestic and foreign experts on the possibility of introducing electronic retail trade of drugs in Ukraine was studied [4–8, 9–16]. It is emphasized that the improvement of legal acts in force in Ukraine in this area is due to the practical necessity of this type of activity in connection with restricted movement and reduced physical accessibility of the population of Ukraine to medicines due to pandemic coronavirus infection (COVID19) [4–8, 9–16].

At the second stage the necessity of carrying out research is substantiated, its purpose and tasks are defined, methods are chosen. A number of previously unresolved issues were identified, namely: gaps in the licensing conditions of retail selling medicines online in relation to the requirements for business entities, qualification requirements for the personnel that will collect, process, form the order and pharmaceutical care of the consumer during the online purchase of medicines; lack of legal requirements for own delivery service of pharmacies, telecom operators and transport companies that will deliver medicines to the end user; lack of a legal mechanism for state control (supervision) of retail selling medicines online at all stages in order to prevent the circulation of low-quality, counterfeit and unregistered medicines.

Registration of results of work and conclusions, formulation of directions of improvement of the legislation of Ukraine in the field of online retail selling (distance selling) of medicines, was carried out at the third stage of the research.

3. Materials and methods

The materials of the study were the legislation of Ukraine and the EU on e-commerce and retail selling of medicines through information and communication tools.

The following methods were used during the study:

- system-analytical (clarification of the level of the research of the problem in domestic and foreign literature);
- content analysis (elaboration of the provisions of the regulations governing the retail sale of medicines through information and communication tools, as well as to understand and interpret the content of certain legal norms);
- comparative legal method (comparison of the features of the mechanism of legal regulation of pharmaceutical assistance to the population in the EU and in Ukraine for further proposals to improve the current Ukrainian legislation in this area);

– graphic methods were used to visualize the results of the research and schematic representation of a number of provisions.

4. Research results

The legal basis for the introduction of online retail trade of medicines in the EU is the provisions of the EU Directives “Directive on electronic commerce” (EU Directive 2000/31/EU) and “Community code relating to medicinal products for human use” as amended (EU Directive 2001/83/EU), which establish the basic principles and rules of retail sale of medicines through information and communication tools [17, 18].

The EU Directive on e-commerce promotes the creation of a legal framework to ensure the free movement of goods and services between EU countries, identifies the main subjects of the relationship in the process of e-commerce of goods and services, and approves the basic concepts of transactions arising in the results of e-commerce (the procedure for concluding contracts using electronic means, placing orders with the consumer, etc.) [17].

It should be noted that the regulatory framework for the circulation of drugs in the EU, including the use of information and communication tools is EU Directive 2001/83/EU, which regulates the online retail selling (distance selling) of medicines is regulated by Section VIII “Sale of drugs to the public at a distance”. According to Section VIII of the Directive, each EU member state can introduce a new type of pharmaceutical activity on its territory – online sales of medicines to the public [18], and the participants in this process are the entities presented in Fig. 1.

An analysis of the legal norms contained in Section VIIA “Sale at a distance to the public” of EU Directive 2001/83/EU, allows us to state that in the field of retail selling medicines online the relevant government agency has the following main functions:

- control over compliance with the legislation in the field of retail selling medicines online;
- providing information on national pharmaceutical legislation on drugs that are allowed for e-retail, differences in legal norms between EU countries regarding the classification of medicines and the conditions of their implementation;
- maintaining the Register of business entities that are allowed to carry out retail selling medicines online with their names, start date of the specified activity and the address of the website used to sell drugs to the final consumer;
- informing about the risks associated with the purchase of drugs through information and communication tools, measures to prevent counterfeit drugs from entering legal circulation by approving and implementing a common logo, its function and purpose of use.

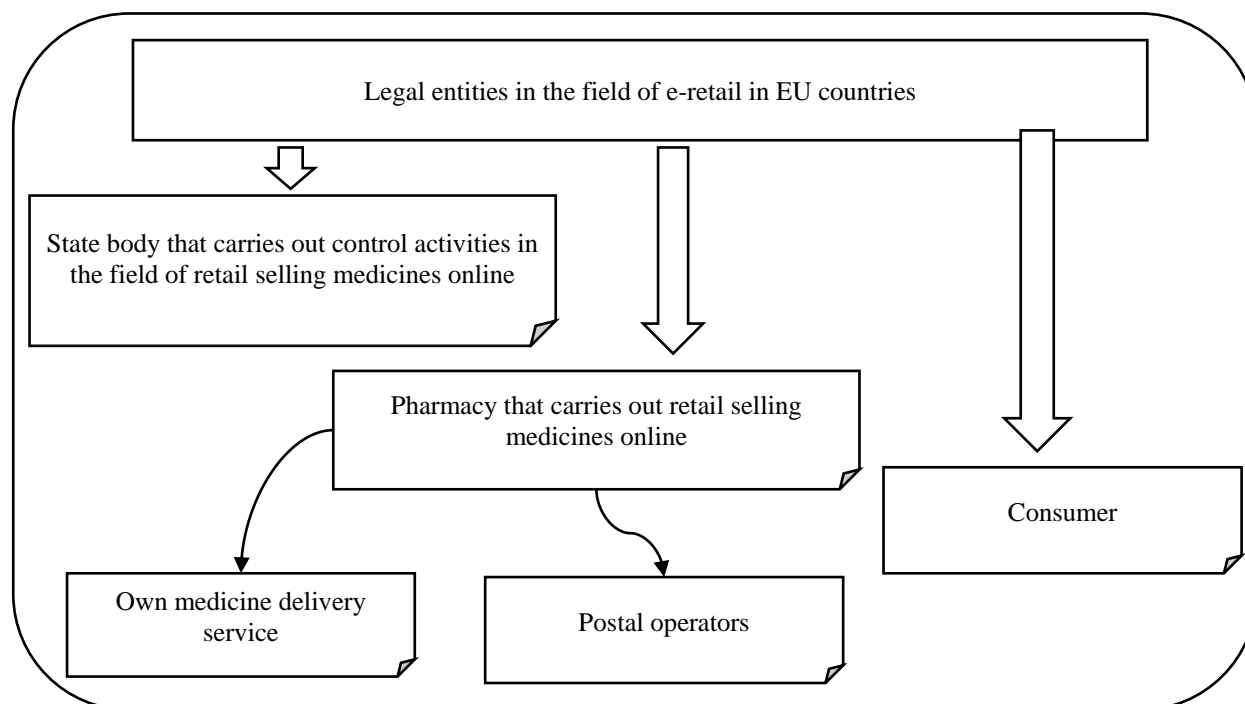


Fig. 1. Subjects of legal relations in the field of the online retail selling (distance selling) of medicines in accordance with Section VIII of EU Directive 2001/83/EU

Another e-retailer is a pharmacy, which must be in a proper way registered in the EU Member State as a legal or individual entrepreneur, have a Retail License and comply with the licensing conditions approved by the EU legislature. In this case, each such pharmacy must be recorded in the Register of business entities engaged in online retail selling of medicines through information and communication tools, and have a website with the following information:

- name of the pharmacy and its address;
- name and address of the state controlling body that exercises control over the conduct of online retail selling of medicinal products;
- data on the availability of a license that allows to carry out activities related to the online retail selling (distance selling) of medicines;
- a common logo, which is a link to the Register of pharmacies that are allowed to carry out online retail selling (distance selling) of medicinal products.

An equally important subject of e-retail of medicines is the end consumer, who buys medicines through information and communication tools. The main task of the EU regulatory authorities in the health care system is to ensure the consumer of proper quality of medicines and prevent the entry of counterfeit medicines, which can lead to negative consequences for his life and health.

In order to protect consumer rights and prevent the negative consequences of the use of counterfeit medicines, the Council of Europe has developed a number of measures to prevent the circulation of counterfeit medicines, and which introduced legal liability for e-retailers for these actions [9–16, 19].

At the next stage of the study, an analysis of the Ukrainian pharmaceutical legislation on the regulation of online retail selling (distance selling) of medicines [11–13, 15, 16]. It should be noted that in Ukraine the formation of the legal framework for this type of activity is at an early stage.

It is established that in Ukraine the legal basis for the introduction of retail selling medicines online consists of several regulations, different in legal force (Table 1).

The analysis of the current legislation of Ukraine on conducting business activities related to e-retail trade of medicines allows to identify several entities, namely: the state regulatory authority, pharmacy, and the end user, as well as the entity whose activities are aimed at delivery of medicines from the pharmacy to the final consumer (postal operator on the basis of contractual relations, own delivery service of medicines, etc.).

According to the Law of September 17, 2020 No. 904-IX “On Amendments to Article 19 of the Law of Ukraine “On Medicines” on the implementation of electronic retail sale of medicines” responsibility for the quality of such drugs purchased through retail selling medicines online, at the stage of their delivery to the end consumer, is a pharmacy [3]. The State Service of Ukraine for Medicines and Drug Control (State Medical Service) has been designated as the state body to control the procedure for conducting retail selling medicines online [3]. But assigning such a function to this body and the procedure for conducting this control requires appropriate amendments to the Regulations on this body [20].

Table 1

The results of generalization of the provisions of the regulations of Ukraine on the regulation of the online retail selling (distance selling) of medicines

| The level of the regulations hierarchy by legal force | Regulation title | The main content of legal norms on the regulation of retail selling medicines online |
|---|---|---|
| The highest level | Constitution of Ukraine | The human right to health is enshrined |
| I level | Law of Ukraine of September 3, 2015 No. 675-VIII "On e-commerce" (as amended on 01.08.2021) | The organizational and legal principles of economic activity in the field of e-commerce (e-commerce) in Ukraine, the rights and responsibilities of participants in relations in this area are determined |
| | Law of Ukraine of April 4, 1996 No. 123/96-VR "On Medicines" (as amended on 08.08.2021) | Legal relations related to quality control and trade in medicines have been settled. The basic legal norms on the implementation of electronic retail trade of drugs and the degree of responsibility for violation of the rules of release and delivery of medicines in accordance with the law |
| II level | Resolution of the Cabinet of Ministers of March 23, 2020 No. 220 "On Amendments to the Licensing Conditions for Economic Activity in the Production of Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines" (except for active pharmaceutical ingredients) (as amended on 23.03.2020) | It is established that in case of quarantine or state of emergency, licensees who have a license to conduct business in retail trade of drugs are allowed to trade drugs and related goods remotely, organize and deliver them directly to consumers in compliance with storage conditions specified by the manufacturer during their transportation, in particular with the involvement of postal operators on a contractual basis |
| | Resolution of the Cabinet of Ministers of November 30, 2016 No. 929 "On approval of the License conditions for economic activity in the production of medicines, wholesale and retail trade of medicines, import of medicines" (as amended on 01.10.2021) | It contains an exhaustive list of requirements that must be met by the licensee and an exhaustive list of documents attached to the application for a license to conduct business in the retail selling of medicines |
| III level | Order of the Ministry of Economy of Ukraine of April 19, 2007 No. 103 "On approval of the Rules of sale of goods to order and outside commercial or office premises" (as amended on 02.10.2020) | The relationship between the consumer and the seller of goods to order and outside trade or office premises on the basis of a contract of sale concluded at a distance or outside trade or office premises is regulated, as well as requirements for consumer rights to proper quality, safety and proper trade services |

In addition, the State Medical Service is obliged to register business entities that plan to sell retail medicines with the help of information and communication tools and maintain a Register of business entities that plan to carry out this type of drug activity [3]. However, the structure of the said Register and the procedure for registration of such pharmacies are not defined in any regulations.

The Law of September 17, 2020 No. 904-IX also contains a provision that a pharmacy may carry out retail selling medicines online, who has a license to retail medicines [3]. In this regard, there is an urgent need to develop and adopt legal norms on the structure of the Register of pharmacies that can retail medicines with the help of information and communication tools, as well as the procedure for its maintenance.

Analysis of the content of the provisions of Art. 19 of the Law of Ukraine "On Medicines" allows us to conclude that the basic requirements for pharmacies that plan to conduct online retail selling (distance selling) of

medicines, comply with the legal norms contained in Directive 2011/83/EU, namely:

- the pharmacy must have a license to carry out activities in the retail sale of medicines;
- have the material and technical base that meets the requirements of the License Conditions for the retail sale of medicines, approved by the Resolution of the Cabinet of Ministers of November 30, 2016 No. 929 [21];
- ensure the delivery of medicines to the final consumer through its own delivery service or such a service with which there is a contractual relationship for the supply of medicines to the final consumer;
- have a website on which online retail selling of medicines will be conducted, which meets the requirements of the Law of Ukraine № 904-IX [3].

In addition, the legislator outlined the basic requirements for filling the website with the following mandatory information:

- availability of information on contact details of the body for licensing and quality control of medicines (State Medical Service);

- placement on all tabs of the site logo with a hyperlink to the Register of business entities that have the right to carry out retail selling medicines online;

- availability of the possibility of conducting pharmaceutical care at all stages of retail selling medicines online;

- indication of information on the cost of medicine delivery.

That is why one of the urgent tasks of lawmaking is to approve the design of the logo with a hyperlink to the specified Register.

In addition, there are gaps in the legislation of Ukraine regarding the establishment of legal liability for the sale of counterfeit and low-quality medicines through information and communication tools, which increases the risk of such medicines reaching consumers and, consequently, negative impact on their lives and health.

5. Discussion of research results

According to the results of the study, topical issues related to the development of legal norms, as well as organizational measures necessary for the introduction of retail trade of medicines through information and communication tools, which are proposed to be divided into several areas (Fig. 2).

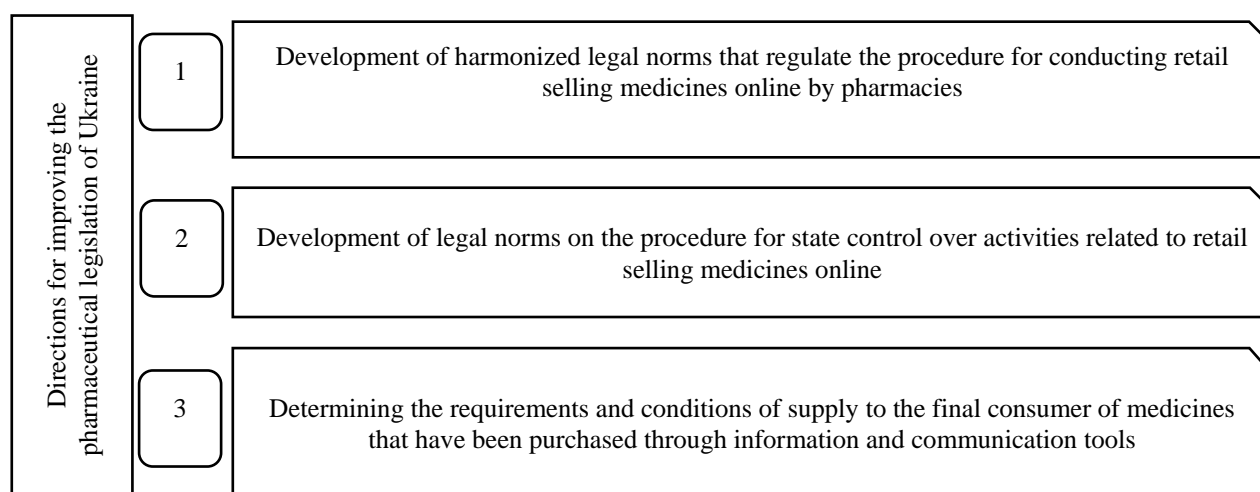


Fig. 2. Directions for improving the pharmaceutical legislation of Ukraine in the field of the online retail selling (distance selling) of medicines

Legislative and organizational work in the first direction should be aimed at:

- defining clearer requirements for pharmacies that are allowed to conduct online retail selling of medicines, taking into account the experience of EU member states and making additions to the Licensing Requirements [21];

- development of standard working methods (standard operating procedures) for online retail selling of medicines;

- determination of the order of registration of orders and dispatches of medicine orders, which are realized by means of information and communication means, and the form of the corresponding magazine in paper or electronic form, which will meet the requirements of the Law of Ukraine “On electronic documents and electronic document management” [22].

In the second direction, it is advisable to develop legal norms in which to establish:

- Regulations on the State Medical Service on the introduction of a supervisory function for the implementation of activities related to retail selling medicines online [17];

- a list of normative legal acts that regulate the procedure and frequency of inspections by the State Medical Service of pharmacies that carry retail selling medicines online for the quality of medicines;

- the structure of the Register of pharmacies that are allowed to carry out retail selling medicines online and the procedure for its maintenance;

- positions and qualification requirements for pharmaceutical workers who have to provide pharmaceutical care to consumers when making online purchases of medicines.

To achieve the goal of the third direction it is necessary:

- to introduce a new type of economic activity subject to licensing - delivery of medicines to the final consumer in e-retail and requirements for them;

- adopt relevant legal norms, which are also responsible for the quality of medicines at the stage of delivery to the final consumer and the transport service (the person who delivers medicines);

- develop legal norms that will set out the mandatory requirements necessary to ensure proper conditions for the transportation of medicines that require special storage conditions.

- to develop and approve a logo for Ukraine, which would act as a link between the website of a pharmacy that carries out retail selling medicines online, and the Register of pharmacies that are allowed to carry out this type of activity;

- establish legal liability for violation of the rules of online retail selling of medicines or the sale of counterfeit or substandard medicines in the course of such activities.

Study limitations. The study of approaches to the formation of the general principles of EU and Ukrainian legislation in the field of the online retail selling (distance selling) of medicines has been studied. A limitation of the study was the study of national legislation of the EU, taking into account the peculiarities of the traditions of national legal systems of different countries.

The prospect for further research. We consider the analysis of the legislation of Ukraine and foreign countries on legal liability for violation of the rules of online retail selling of medicines to be a promising area of further research in this area.

6. Conclusions

The study of approaches to the formation of EU and Ukrainian legislation on the online retail selling

(distance selling) of medicines, highlighted the legal status of the subjects (participants) of this process.

Based on the elaboration of norms regulating retail selling medicines online, the need to further improve the current pharmaceutical legislation of Ukraine in this area in order to harmonize it with the legal norms of the relevant EU Directives is substantiated, and specific areas of such activities are proposed.

Conflicts of interest

The authors declare that there is no conflict of interests.

Financing

The study was performed without financial support.

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Received date 08.06.2021

Accepted date 21.10.2021

Published date 29.10.2021

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