

СЕКЦІЯ 9. ФАРМАЦЕВТИЧНІ НАУКИ

IMPROVEMENT OF LEGAL FRAMEWORK OF PHARMACEUTICAL ACTIVITY IN UKRAINE

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In the conditions of development of market relations, it is urgent to improve the legal bases of pharmaceutical activity by improving the regulatory framework and other laws of Ukraine.

According to the results of the analysis of the legal field for regulating the promotion of goods on the pharmaceutical market, it is established that the main legal acts that determine the requirements for improving pharmaceutical activity are the Laws of Ukraine («Fundamentals of Ukrainian Health Legislation» dated 28.11.1992 No. 2801-XII, «About medicines» from 04.04.1996. № 123/96-BP, «On Advertising» dated 03.07.1996. № 270/96-BP, «On Protection from Unfair Competition» of 07.06.1996. No. 236/96-BP, "On the Protection of Economic Competition» of 11.01.2001 No. 2210-III), on the establishment of the Cabinet of Ministers of Ukraine («On approval of licensing conditions for the implementation of economic activities for the production of pharmaceuticals, wholesale, retail trade in medicines, import of medicines (excluding active pharmaceutical ingredients)» No. 929 of 30.11.2016) and orders of the Ministry of Health of Ukraine («On some issues on the prohibition of advertising of medicines" dated 06/06/2012. № 422, «On approval of the List of medicines banned for advertising, which are released in recipe «06.11.2012 year № 876).

To date, state regulation of prices is directed to the pharmacy network. If we talk about the analysis of the results of the enterprise for many years, we can say that the pricing policy of the pharmacy institution ultimately determines a tough competitive environment, limiting the use of high premiums.

Despite the growth in sales for the last five years by 2.5 times in comparable prices, the level of profitability of the enterprise has decreased from 6.4% to 1%. Therefore, problematic issues of pricing should be paid close attention at the level of both the legislative and executive authorities.

The most important document for doctors in Ukraine is the Law «Fundamentals of Ukrainian legislation on health care», which defines the legal, organizational, economic and social health care in Ukraine, regulating social relations in this area.

Article 38. Choosing a doctor and a health care institution. Every patient who has reached the age of fourteen and applied for medical assistance is entitled to

free choice of a doctor if the latter can offer his services and the choice of treatment methods in accordance with his recommendations [5].

Each patient has the right, if justified by his condition, to be admitted to a health institution of his choice, if that institution is able to provide appropriate treatment.

It should also be noted that today medicines are financed by 86% at the expense of the consumer. Hospital sales account for only 6% of total drug sales through various channels. Speaking about the dynamics of segments of the retail market in 2017, it should be noted that in packages negative dynamics is demonstrated by all segments, except for goods for patient care. In the hryvnia sense of dynamic growth occurs in the segment of dietary supplements and prescription drugs. Moreover, OTC drugs demonstrate dynamics, worse from the prescription group [1, p.12].

High growth rates of domestic companies were also noted compared to foreign ones. Speaking about the tender procurement segment: the amount of purchases for all products, including centralized purchases, donor organizations, tender purchases and purchases by regional departments and hospitals, for the first 11 months of 2017 amounted to 6400000000 hryvnas.

In 2017, the most significant growth indicators were demonstrated by the segment of centralized purchases, as well as the segment of direct tenders for hospitals (in 2017, 21%). By own means giving discounts to veterans and pensioners, the enterprise,

In addition, it constantly distracts working capital for lending holidays for free and preferential recipes. And speaking of monopolizing the pharmaceutical market, it is a ballast of the economy of an enterprise whose existence is justified only by social necessity.

In accordance with the norms of the European Union and the requirements of the Resolution of the Cabinet of Ministers No. 1419 in Ukraine, the final period of transition to GMP and GDP standards is determined. And this means that it is necessary to bring not only a material basis in line, but also an adequate regulatory and legal regulation of pharmaceutical activity. But the legislative settlement remains one of the main problems not only for the industry, but for the state as well. Pharmacy structures of various forms of ownership and subordination mostly function as trade organizations, not complying with legislative requirements for pharmaceutical activities.

It should be noted that the current legislation does not cover all aspects of the production, circulation and sale of medicines. The new regulatory framework, adapted to the requirements of the European Union and the realities of the Ukrainian economy, has been a subject of discussion for a long time.

Changes in the legislation will allow to reduce the registration period of medicines of both domestic and imported production, to put barriers on the way of adulteration of falsified and low-quality products to the Ukrainian market. The State Service of Medicines and Medical Products has recently been carrying out purposeful work on the preparation of the regulatory and legal framework.

The establishment of a working group in the Ministry of Health of Ukraine, whose main task is to coordinate and develop the necessary documents, contributes to a purposeful approach to the development of draft normative acts involving the broad masses of the public. To date, some of the developed projects have already been approved and used in practical pharmacy, the other part requires in-depth analysis and actualization.

The current legislation requires further development of the purchase of medicines and medical products, taking into account the specifics of health care.

Speaking about the priorities of the pharmaceutical industry, it is also necessary to develop and support our own production. As for manufacturing in a pharmacy, the trend is a sharp reduction: production pharmacies account for only 7.5% of the total number of pharmacies in Ukraine. Such a situation can not in any way contribute to increasing the population's access to effective, safe and quality medicines, improving the state of drug provision.

The problems of intra-pharmacy production are not only in the material and technical base, which can be brought into correspondence, having temporary, human and significant material resources. There is a significant number of registered substances and glass of the corresponding brand. Without addressing these problems, the high requirements laid down in regulatory documents will not be met.

Draft Law of Ukraine «About Medicinal Products» No. 2162 of 17.02.2015. According to this project, the project envisages an indirect mechanism for influencing the delivery of medicines. The new section contains a number of articles that were not included in the current version of the Law: Section IV «BASIC PRINCIPLES OF APPLICATION OF MEDICINES IN MEDICAL PRACTICE», which determines that the appointment medicines should be carried out exclusively on medical and technological documentation and forms, which must be of three levels: state, regional, and building a new system [2, p.10].

Also, an important problem for the solution of which is the project of accessibility of high-quality medicines, rational use of them and their intended use.

To resolve this problem, the draft provides for a new section, which contains a number of articles that were not in the current version of the Law.

For example, Section V. PHARMACEUTICAL PRACTICE, in particular, the concept of pharmaceutical services and assistance aimed at ensuring the effectiveness of pharmacotherapy, by providing appropriate recommendations to the patient on the consistency and proper use of medicines that the doctor appointed, interaction with the doctor, in case of questions the compatibility of drugs that are intended, and the like. Compliance with punctures regulating the effect of the pharmacist on self-medication without a prescription group of medicines [4].

It should be noted that the section provides for the creation of a system of state pricing for medicines. The implementation of the norms of this section will become the basis for measures to ensure the availability of effective therapy for a

wide range of the population of Ukraine.

Section VI. ADVERTISEMENT OF DRUGS OF THE PROJECT, containing:

- 1) reducing administrative pressure on pharmaceutical market operators, increasing the level of transparency when introducing drugs to the Ukrainian market and, as a consequence, reducing the level of corruption during the circulation of medicines;
- 2) protecting consumers from dangerous, inefficient and substandard medicines; legislative basis for normal competition among business entities; access of high-quality medicines to the Ukrainian market;
- 3) decrease in the cost of medicines.

The main problem is that until now there is no clearly defined at the state level development strategy of the industry, and the pharmacy segment in particular.

Conclusions: Based on the above, it can be noted that the main factors that will affect the improvement of pharmaceutical activity in Ukraine in 2018, can be called:

- 1) a change in the pricing model for medicines, introduction of reimbursement (the reimbursement program for medicines "Available medicines" will be extended to drugs that are used in pre- and postoperative period for organ and tissue transplantation in July 2018.

According to the Decree of the Cabinet of Ministers of Ukraine of December 27, 2017, which will come into force on July 1, 2018, four international non-patent names (INN) - azathioprine, mycophenolic acid and its salts, tacrolimus, cyclosporin) are included in the list of drugs,

- 2) as well as the transition to the new National List of Medicines.

The proposed draft Concept for the development of the pharmaceutical industry contains many questions:

- 1) professional training of person;
- 2) support of the domestic manufacturer, creation and support of the quality assurance system;
- 3) mechanism for the development of production of immunobiological drugs.

which together we will go to a new level of organization of drug provision.

These are the main issues that can not be postponed any longer. And we hope that the work of the congress will help to update these issues to the Ministry of Health and the Government of Ukraine. It should also be noted that the pharmaceutical industry needs state support.

References:

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3. The Law of Ukraine «Fundamentals of Legislation of Ukraine on Health