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КОНТРОЛЬ ЯКОСТІ ЛІКАРСЬКИХ ЗАСОБІВ: ЗАРУБІЖНИЙ ДОСВІД

CONTROL QUALITY OF MEDICINES: FOREIGN EXPERIENCE

Анотація. Автором досліджені системи державного контролю якості лікарських засобів провідних країн Європи (держав-членів ЄС) та США. Проаналізовано зарубіжний досвід проведення перевірок таких країн як: Великобританія, Хорватія, Латвія, Польща. Встановлено, що вітчизняна система держлікконтролю є більш справедливою та ризик-орієнтованою (оскільки, на відмінну від Польщі, відбір зразків направлений, в першу чергу, на ті лікарські засоби, які перебувають в обігу з порушенням чинного законодавства; періодичність проведення перевірок в Україні диференційована залежно від ступеня ризику господарської діяльності на відміну від Великобританії, Хорватії, Латвії; розподіл витрат в Україні на проведення лабораторного дослідження залежить від результатів лабораторного дослідження якості лікарських засобів, у Великобританії всі витрати несуть підприємці тощо). Встановлено, що в Україні побудовано ефективну систему державного контролю якості лікарських засобів, яка не поступається системі контролю якості таким країнам як Хорватія та Польща. Зокрема, встановлено, що статус, структура,

повноваження суб'єктів контролю в Україні, Хорватії та Польщі ідентичні, як і процедура інспектування та відбору зразків. В деяких питаннях українське законодавство навіть випереджає за розвитком законодавство вищенаведених країн (це стосується ризик-орієнтованості системи державного контролю якості лікарських засобів, посилення захисту прав суб'єктів господарювання під час інспектування, справедливості у питанні розподілу витрат на лабораторні дослідження між підприємствами та державою). Обґрунтовано необхідність у створенні системи захисту прав споживачів у фармацевтичні сфері, яка на сьогодні фактично відсутня в Україні. Такі обґрунтування спираються на зарубіжний досвід Франції, Німеччини, Данії. Пропозиція полягає в створенні можливості фізичних осіб у разі обґрунтованої підозри щодо неякісності придбаного лікарського засобу звернутися до територіальних органів Державної служби України з лікарських засобів та контролю за наркотиками для проведення його лабораторного аналізу. За результатами експертних висновків щодо неякісності фармацевтичної продукції Державної служби України з лікарських засобів та контролю за наркотиками матиме всі підстави для проведення позапланової перевірки, а фізична особа – докази для судового захисту свої прав. Встановлено, що процедура інспектування та відбору зразків лікарських засобів для лабораторного аналізу в Польщі та Україні ідентичні.

Ключові слова: контроль якості лікарських засобів, якість лікарських засобів, лікарські засобі.

Summary. The author researched the systems of state quality control of medicines of the leading countries of Europe (EU Member States) and the USA. Foreign experience in conducting inspections of such countries as: Great Britain, Croatia, Latvia, Poland is analyzed. It has been established that the domestic system of SMDC is more fair and risk-oriented (since, unlike Poland, sampling is directed, first of all, to those medicinal products that are in circulation in violation orlegislation; the frequency of inspections in Ukraine is differentiated depending on

the degree of risk of economic activity, in contrast to the UK, Croatia, Latvia; the distribution of costs in Ukraine for laboratory research depends on the results of laboratory research of the quality of medicines, in the UK all costs are borne by entrepreneurs, etc.). It was established that an effective system of state quality control of medicinal products has been built in Ukraine, which is not inferior to the quality control system to such countries as Croatia and Poland. In particular, it was established that the status, structure, powers of the subjects of control in Ukraine, Croatia and Poland are identical, as well as the procedure for inspection and sampling. In some matters, UkraineThe legislation is even ahead of the development of the legislation of the above-mentioned countries (this concerns the risk-orientation of the system of state quality control of medicines, strengthening the protection of the rights of business entities during inspection, fairness in the distribution of costs for laboratory tests between enterprises and the state). The need to create a system of consumer protection in the pharmaceutical sector, which is currently virtually absent in Ukraine, is justified. Such justifications are based on the foreign experience of France, Germany, Denmark. The proposal is to create an opportunity for individuals, in case of reasonable suspicion of the poor quality of the purchased medicinal product, to apply to the territorial bodies of the State Service of Ukraine on Medicines and Drugs Control for its laboratory analysis. According to the resultand expert opinions on the poor quality of pharmaceutical products of the State Service of Ukraine on Medicines and Drugs Control will have every reason to conduct an unscheduled inspection, and an individual will have evidence for judicial protection of his rights. It was established that the procedure for inspection and sampling of medicinal products for laboratory analysis in Poland and Ukraine is identical.

Key words: quality control of medicinal products, quality of medicinal products, medicinal products.

An overview of the research issue. Trends in the development of the pharmaceutical sector of the economy, an increase in the number of drugs on the market

and an increase in profitability from their sale inevitably lead to the appearance of low-quality and falsified pharmaceutical products. Medicinal products are specific products, the quality of which directly depends on the life and health of the population. In addition, the circulation of medicines is connected with their use in the networks of state health care institutions, and this increases the state's responsibility to the population. Realizing this, every country in the world is trying to build an effective national drug quality control system, the main goal of which is to ensure public access to high-quality, effective, safe pharmaceutical products. Ukraine is no exception. However, in the conditions of a free market economy, there is a need to maintain a rational balance between ensuring public access to safe and high-quality pharmaceutical products by establishing a system of strict state control and stimulating the development of entrepreneurial activity in the pharmaceutical field, protecting the interests of economic entities during the implementation of state measures control In addition, European integration, and in the future, the creation of a single European pharmacological market with EU countries, requires further analysis of the legal regulation of the quality control systems of medicinal products during their circulation in individual EU countries.

The purpose of this paper consists in a comprehensive and thorough characterization of the peculiarities of the legal regulation of the state accounting control , highlighting theoretical and practical problems and finding ways to solve them.

The analysis of recent publications and research. The empirical basis of the research is domestic normative acts, as well as legislative acts of foreign countries, materials of judicial and law enforcement practice, statistical data.

Scientific works served as the theoretical basis of the work:

a) specialists in medical law - V.M. Pashkova, O.A. Khmelnytska, S. V. Vasiliev, V. Lazareva, A. O. Olefira, A. S. Nemchenko , R. I. Podkolzina , L.G. Cherkovskaia , L. O. Avramenko, D. Yu. Skoryna, O.P. Baumy , I.S. Chekman ,

A.O.Syrova , O.M. Tsiborovskyi , L. Bardakova , L.O. Fedorova, N. O. Vetyutneva and others;

b) scientists who studied the theoretical foundations of the construction of the state control system - V.B. Averyanova, E. Pushko- Tsybulyak , A. A. Bolukha , V.P. Dudko, A.V. Malysheva, S.G. Rozhkov and others;

c) scientists who analyzed the international legislation on quality control of medicinal products, as well as the cooperation of states in the field of quality control of medicinal products at the international level - A.V. Aleksandrova , D. Bruner , V.S. Malichenko , O. Ternovenko and others.

The scientific and practical significance of these problems, their insufficient development in doctrine, as well as the debatable nature of many issues determined the choice of the topic of this study.

Presentation of the material. In the world, the modern understanding of approaches to quality assurance is based on the comprehensive concept of the quality assurance system [1]. This concept covers ensuring the quality of medicinal products, starting from the stage of their development and research through production, quality control, storage, distribution, and ending with the provision of information to the doctor and patient [2]. It consists of: 1) direct quality control; 2) quality assurance (a system based on quality forecasting through the implementation of GLP, GCP, GMP, GDP, GPP, GSP, or in other words, the so-called "6 sigma" system; 3) quality management (ISO standardization).

Quality control is theoretically the first concept based on the position of uniformity in the quality of products and samples taken for control.

An important point to understand is the separation from state drug control of such a form of post- registration control as pharmacovigilance .

Due to the fact that, firstly, pharmacovigilance and state drug control refer to the post- registration type of quality control of medicinal products and have the sole purpose of identifying and withdrawing substandard products from circulation, secondly, they exist in parallel with each other, thirdly, in the 2001 Directive /83/EC

of the European Parliament and the Council of the EU dated 06.11.2001 "On the compilation of Community laws regarding medicinal products for humans" [3] many articles are devoted to these quality control systems, fourthly, the population and medical personnel are actually not properly familiar with the system of pharmacovigilance (does not distinguish the system of quality control of medicinal products from the system of pharmacovigilance) , there is an urgent need for a clear distinction between these two concepts.

The system of state control , as one of the functions of state administration in the sphere analyzed by us, consists of a number of elements.

In particular, such elements are: 1) legal regulation; 2) subject of control; 3) subject of decision-making based on control results; 4) object and subject of control; 5) purpose, tasks, principles of control; 6) control process [4].

In order to provide a comprehensive description of the state medical control system , to identify the existing shortcomings of this system and to make proposals for its improvement, an analysis of the above elements is necessary. In addition, in connection with the European integration processes and the creation of a common pharmaceutical market with the EU countries, it is necessary to conduct a comparative analysis of the quality control systems of medicinal products of Ukraine and individual EU member states for compliance with European standards.

Since 2014, the administrative status, structure, and powers of the State Medical Service are mostly similar to the status of the Polish Chief Pharmaceutical Inspectorate (with the exception of licensing powers), which consists of the Chief Pharmaceutical Inspectorate of the Republic of Poland and 16 territorial provincial inspectorates with 10 authorized laboratories [5] and the Croatian The Agency for Medicinal Products and Medical Devices [6]. And although the number of inspectorates in Poland is smaller, and the number of laboratories is the same as in Ukraine, however, the territory of Poland, the number of population and the number of pharmaceutical establishments are smaller. In addition, in Poland, a system of multiple institutions for the regulation

of the pharmaceutical market, and in particular, the state drug control system, has been implemented .

Note that despite the extremely large range of tasks, the performance of which is directly related to public health, the staffing of territorial bodies of the State Medical Service is quite small compared to the staffing of other central executive bodies. Although with the implementation of the requirements provided for by Directive 2011/62/EU, regarding the creation of an automated system of tracking in the circulation of medicinal products from the manufacturer to the final consumer using labeling (codification) and identification GS1 [7], the existing number of specialists of the State Medical Service will be sufficient for the effective performance of tasks, related to the quality control of medicinal products during their circulation.

In particular, in the State Medical Service of Ukraine, the maximum number of employees is 254 (including staff), and in its territorial subdivisions - 740 people (including staff) [8]. As of 2016, there were only 2 authorized inspectors working in the Poltava region (subjects of conducting control measures and making decisions based on the results of such measures).

In view of the above, we believe that the permanent proposals to reduce the number of territorial bodies of the State Medical Service from 25 to 7 (with a corresponding staff reduction) [9] are impractical. Such changes (the last ones were proposed on December 11, 2017) will make it impossible to fulfill the tasks of the State Medical Service and will lead to the absence of its full-fledged representation on the territory of Ukraine, which can be considered a negative trend, taking into account the increase in the number of pharmaceutical enterprises.

In addition, the decrease in staff and structural numbers of the State Medical Service will not allow to introduce a system of consumer rights protection in the pharmaceutical sector, which is currently absent. We are talking about the possibility of consumers of pharmaceutical products to apply to the territorial bodies of the State Medical Service for laboratory analysis (in specialized certified laboratories) of the purchased medicinal product in case of reasonable suspicion of its poor quality. The

presence of a conclusion that the medicinal product is of poor quality is a valid evidence and a reason for the consumer to apply to the court to protect his rights.

This practice is characteristic of France, Germany, Switzerland, Denmark and other countries of Western Europe with the only condition - if the medicinal product is of high quality, the costs of the examination are borne by the applicant.

Currently, the following quasi- system of consumer rights protection in the pharmaceutical sector operates in Ukraine - citizens have the right to appeal to the State Medical Service with a complaint about the questionable quality of a medicinal product. However, the State Accounting Service can carry out an unscheduled control measure only after prior agreement with the DRS of Ukraine or after obtaining permission directly from the business entity itself. The State Medical Service does not have the right to analyze a medicinal product at the request of a consumer

Thus, the main goal of the SMDC system is to ensure access to safe and high-quality medicines. The principles of state control are contained in Art. 3 of Law No. 877-V (which is a generally binding, special norm). The list of principles in 2016 was significantly updated and supplemented. In particular, such as: 1) presumption of legitimacy of the activity of a business entity in case of multiple interpretation of rights and obligations; 2) focus of state supervision (control) on the prevention of offenses in the field of economic activity [6] (for example, by consulting regulatory authorities); 3) preventing the establishment of planned indicators or any other planning to bring business entities to justice and apply sanctions to them; 4) implementation of state supervision (control) on the basis of the principle of risk assessment and expediency [6]. As we can see, the new principles reflect Ukrainian realities (the presence of legislative conflicts, planned indicators, etc.).

According to Art. 13 of Law No. 123/96-VR, the state control is carried out by the executive authorities within the limits of powers determined by the legislation of Ukraine. According to Art. 14 of the above-mentioned Law, control over the quality of medicinal products is carried out by the central executive body that implements the state policy in the field of quality control and safety of medicinal products [7].

According to clause 1 of Regulation No. 647, the subject of quality control of medicinal products in Ukraine is the State Service of Ukraine on Medicines and Drugs Control [8], which was established in 2014 through the merger of two services (the State Service for Drug Control and the State Service for Medicines). Unification means a combination of powers and functions of two central executive bodies in one, but their structure has been significantly optimized, in other words, it has been reduced.

Thus, today the structure of the SMDC is classical (that is, similar to other central executive bodies). It consists of the State Service of Ukraine on Medicines and Drugs Control, headed by the Head of the SMDC (by position is the Chief State Inspector of Ukraine for Quality Control of Medicinal Products [8], who has two deputies[1]) and its territorial bodies (at the level of oblasts and the city of Kyiv, as cities with a special status, headed by heads). Interregional territorial bodies of the State Service for Drug Control were liquidated.

Also, since 2012, the SMDC has 10 laboratories equipped in accordance with WHO recommendations, and the Central Laboratory is retrained by WHO, accredited by the European Directorate for Quality Control of Medicines of the Council of Europe and included in the pan-European network (GEON) of the Official Medical Control Laboratories (OMCL) [1]. Out of 10 laboratories, 5 are located in Kiev (one of them also has branches in Dnepropetrovsk and Lviv), 3 - in Kharkov, and 2 - in Lviv.

Thus, competition in the market is significantly limited, and a business entity often has to bear additional costs for transporting medicines to the laboratory in another administrative-territorial unit. There is a problem of limited competition in the market of such services, which creates preconditions for abuse by regulatory authorities.

In our opinion, the way out of this situation is: 1) creating a competitive environment by providing an opportunity for certification to private laboratories; 2) anticipation of the possibility of a business entity to independently choose from existing certified laboratories the one in which the analysis or establishment of criteria by which the SMDC will choose laboratories and establish grounds for refusing the

possibility of such a choice; 3) development and adoption of a methodology for calculating or estimating the services of authorized laboratories.

The internal structure of the SMDC consists of departments in accordance with the main activities (for example, the licensing department, the quality control department, etc.). The right to carry out control measures and make decisions based on the results of inspections is vested in officials of the State Service of Ukraine on Medicines and Drugs Control. However, it should be noted that the Unified State Register of Inspectors of the State Service of Ukraine on Medicines and Drugs Control does not exist, which, in our opinion, is a disadvantage and makes it impossible for a business entity to verify the legality of control measures by an appropriate entity.

The newly formed body is endowed with a wide range of powers to perform the main tasks in the following areas: 1) quality control of medicinal products when imported into the territory of Ukraine and in their circulation; 2) licensing of economic activity in the production of medicines, import of medicines, wholesale and retail trade in medicines (since 2015); 3) circulation of narcotic drugs, psychotropic substances, their analogues and precursors, , counteraction to their illicit trafficking [8]; 4) certification of laboratories, pharmacists and pharmacists, etc.

Directly in the field of state control, the SMDC in accordance with paragraph 3 of regulation No. 647: a) selects samples of medicinal products in accordance with the established procedure to check their quality; b) carries out state control over compliance with the requirements of the legislation on ensuring the quality and safety of medicinal products at all stages of circulation, including the rules for the implementation of good practices (production, distribution, storage, pharmacy); c) draws up protocols on administrative offenses and considers cases of administrative offenses in cases stipulated by law; d) provides mandatory orders for the elimination of violations of standards and technical conditions, pharmacopoeial articles and technological regulations, as well as on the elimination of violations during the production, storage, transportation and sale of medicines; e) makes decisions in accordance with the established procedure on withdrawal from circulation and

prohibition (suspension) of production, sale and use of medicinal products that do not meet the requirements defined by regulatory legal acts [8]. In addition, the territorial bodies of the State Service of Ukraine on Medicines and Drugs Control carry out about 25 other types of work of internal activities [11] (for example, processing citizens' appeals, generalizing the causes of violations, documenting the process of conducting inspections, etc.).

With regard to subjects of state drug control in the world, attention should be paid to the lack of a single standard or approach to what national control bodies should be and how many there should be. There are no such recommendations in the European directives that draw attention to the need to ensure the performance of a certain range of functions - it does not matter if it is by one body or several) [10].

A system of multiple institutions has been created in Poland. In Hungary, until 2011, there was also a multiple system of state regulation of the pharmaceutical market, but later it was united into a single institution - the National Institute for Quality and Development in the Field of Health Care and Medicines (National Institute for Quality - and Organizational Development in Healthcare and Medicines) [10].

According to the multiple model, a clear division of functions, greater specialization (and therefore higher professionalism) of bodies can be recognized as an advantage, and provided that they are truly independent from each other, a higher level of insurance against errors and the possibility of their correction at the next stage of control, which is carried out by another body . At the same time, the process of managing and coordinating the work of these bodies is more complicated, duplication of functions is possible, a bureaucratic component is added to relationships, which slows down the process of organizing regulatory and supervisory work and making management decisions. Under the model of one body, the efficiency of work increases (internal procedures are always faster than external ones) and bureaucratic operations are reduced and simplified, however, the probability that mistakes will not be detected (due to the lack of additional control) increases. The main thing that unites both the

multiple model and the model of one body is a set of their mandatory functions - licensing and permitting, expert and quality control [10].

So, until 2014, there was a scheme of multiple control institutions in Ukraine, now it is represented by a single institution - the State Medical Service , which in terms of its status (structure, powers, organization of work) is close to the subjects of control in such countries as: Italy (Italian Agency for Medicinal Products (Agenzia Italian Del Farmaco - AIFA), Croatia (**HALMED),** Great Britain (Agency for Quality Control of Medicines (MSA)), Hungary (MIQODHM), Poland (if we talk about the Main Pharmaceutical Inspectorate) and others.

Regarding the object and subject of control, the following should be noted. The object of state drug control is business or non-business entities, which, regardless of the form of ownership or organizational legal form, carry out activities related to one or more stages of the circulation of medicinal products.

A similar list of objects of control can be found in Chapter 8 of the Constitution of Poland " Prawo farmaceutyczne » 2001 [11]. As we can see, the procedure for conducting the state liquor control in Poland is determined exclusively by special legislation.

Thus, in accordance with paragraphs 9, paragraph 4 of Regulation No. 647, the following are the objects under the control of the State Medical Service : medical and preventive facilities (including those that are part of the structure of the Ministry of Internal Affairs of Ukraine (the Department of Health and Rehabilitation of the Ministry of Internal Affairs of Ukraine), the SBU (military medical department)) , pharmaceutical healthcare institutions, military units, universities (for example, Zaporizhia National University), etc. [24, 25]. That is, controlled objects can be divided into two types: 1) classic or typical (pharmaceutical establishments and medical and preventive establishments); 2) non-classical.

It is necessary to focus attention on objects of control, because most often problems arise when non-typical controlled enterprises, institutions, organizations (i.e., not pharmaceutical and medical and preventive institutions) refuse admission to control

bodies for inspection, motivating it by the fact that medicinal products are stored for the purpose of "internal" use (for employees), and since they do not implement them, the inspectors of the State Medical Service do not have the right to check them. However, this practice is wrong and contradicts the norms of the current legislation. All objects that carry out activities in the field of circulation of medicinal products must be inspected periodically depending on the degree of risk.

The subject of control, both in Ukraine and in EU countries, is the quality of medicinal products. According to Art. 1 of Law No. 123/96-BP, the quality of a medicinal product is a set of properties that give a medicinal product the ability to satisfy consumers in accordance with its purpose and meet the requirements established by legislation [12]. That is, during inspections, the State Medical Service analyzes the appearance (labeling), accompanying documents for batches of medicinal products (registration card, medicinal product quality certificate) and selects control samples.

It should be noted that in the EU countries, the concept of "quality of medicinal products" is comprehensive, broader and includes the following concepts: effectiveness, safety, quality. In Ukraine, medicinal products are registered and put into circulation without proving their effectiveness.

There is no regulated quality control procedure at the pan-European level. Directive 2001/83 / EU provides for general requirements for confirmation of quality control through compliance with licensing conditions, including GDP conditions, pharmacovigilance rules . Detailed rules are established in each country separately [13].

Therefore, an important role in the quality assurance system is played by international and regional organizations whose activities are aimed at creating a global and safe pharmaceutical market. For example, the European Medicines Agency (EMA), the European Directorate for the Quality of Medicines and Healthcare (EDQM) , The Pharmaceutical Inspection Convention and The Pharmaceutical Inspection Co-operation Scheme.

In Poland, for example, they form an annual sampling plan and send it to regional offices. The business entity does not have information about which drug and when it will be tested, but a general list of drugs for testing is available

A similar rule is established in Croatia. In Poland and Latvia, all expenses for the selection, delivery and expert research of medicinal products are borne by the state, in contrast, in the UK, on the contrary, the subject of economic activity [10] . The reimbursement system in Croatia and Ukraine appears to be more fair, provided that all requirements and rules are followed during the procedure for the selection of samples of medicinal products.

Therefore, the stage of selection of samples of medicinal products is extremely important during control measures carried out by the State Forestry Service , as the fate of a series of medicinal products and economic activity as a whole depends on its results. From the analysis of court practice, it was established that it is at this stage that the State Medical Service inspectors make the most mistakes. With this in mind, it is necessary to follow the entire sample selection process, carefully study the documents and challenge any illegal actions of the inspectors of the State Medical Service (so that in the end it is not established that a completely different drug was tested [14]).

It is also worth emphasizing that according to Art. 122 and, j , k " Right farmaceutyczne » in Poland, a similar procedure for the selection of samples of medicinal products has been established [14].

Conclusion and proposal. Foreign experience in conducting inspections of such countries as: Great Britain, Croatia, Latvia, Poland is analyzed. It has been established that the domestic system of SMDC is more fair and risk-oriented (since, unlike Poland, sampling is directed, first of all, to those medicinal products that are in circulation in violation orlegislation; the frequency of inspections in Ukraine is differentiated depending on the degree of risk of economic activity, in contrast to the UK, Croatia, Latvia; the distribution of costs in Ukraine for laboratory research depends on the results of laboratory research of the quality of medicines, in the UK all costs are borne by entrepreneurs, etc.). It was established that an effective system of

state quality control of medicinal products has been built in Ukraine, which is not inferior to the quality control system to such countries as Croatia and Poland. In particular, it was established that the status, structure, powers of the subjects of control in Ukraine, Croatia and Poland are identical, as well as the procedure for inspection and sampling. In some matters, UkraineThe legislation is even ahead of the development of the legislation of the above-mentioned countries (this concerns the risk-orientation of the system of state quality control of medicines, strengthening the protection of the rights of business entities during inspection, fairness in the distribution of costs for laboratory tests between enterprises and the state). The need to create a system of consumer protection in the pharmaceutical sector, which is currently virtually absent in Ukraine, is justified. Such justifications are based on the foreign experience of France, Germany, Denmark. The proposal is to create an opportunity for individuals, in case of reasonable suspicion of the poor quality of the purchased medicinal product, to apply to the territorial bodies of the State Service of Ukraine on Medicines and Drugs Control for its laboratory analysis. According to the resultand expert opinions on the poor quality of pharmaceutical products of the State Service of Ukraine on Medicines and Drugs Control will have every reason to conduct an unscheduled inspection, and an individual will have evidence for judicial protection of his rights. It was established that the procedure for inspection and sampling of medicinal products for laboratory analysis in Poland and Ukraine is identical.

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