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SOME FEATURES OF THE OFFENSES CLASSIFICATION PERPETRATED IN THE PHARMACEUTICAL SECTOR OF UKRAINE

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Key words: offense; violation; administrative responsibility; pharmaceutical sector

The problems of offenses classification in the pharmaceutical sector with generally accepted criteria in justice are considered. The main groups of administrative violations in the pharmaceutical sector of public health have been distinguished. Legal relations that appear in the pharmaceutical sector require constant government protection by prevention and detecting of violations in pharmaceutical legislation and the accountability of those who are responsible to justice. We used the formal-legal method for the analysis of normative legal acts that establish administrative responsibility for offenses in the pharmaceutical sector during preparation of the article. Describing the administrative violations in the pharmaceutical sector we find that according jurisdiction of cases it can be conditionally subdivided into three groups: 1. The cases filed for the state bodies of drugs quality control (art. 244-8 Ukrainian Code on Administrative Violations). 2. The cases filed for the executive state bodies for consumer protection (art. 244-4 Ukrainian Code on Administrative Violations). 3. The cases filed for the district, city district, city or city district courts (judges) art. 221 Ukrainian Code on Administrative Violations. We consider that these offenses factors in the pharmaceutical sector will specify the offenses and personalize their subjects, and it will enable to use legal liability action against offenders and oppose to violations in pharmaceutical legislation more effectively.

As stated in the Constitution of Ukraine, every citizen has the right to health care. Ensuring this right should be the main focus of the national state institutions.

According to the famous British statesman Lord Beaconsfield, public health is the base, on which the welfare of people and the power of the state are grounded, taking care of people's health is the first obligation of a statesman.

Legal relations in the pharmaceutical sphere need permanent protection from the government through the implementation of measures to prevent and detect violations of pharmaceutical legislation and to be brought to justice.

Since November 1, 2011, State Administration of Ukraine on Medicinal Products became the full member of the international System of cooperation of pharmaceutical inspections (Pharmaceutical Inspection Cooperation Scheme – Pic/s). Ric/s is an international instrument of interaction between the countries and their regulatory bodies in the sphere of control of quality of medicines (national pharmaceutical inspectorates), which provide together the active and constructive cooperation in the sphere of the Good manufacturing practice (GMP), inspection and licensing. Regulatory bodies of the participating countries of Pic/s carry out continuous exchange of information concerning standards of production and distribution of medicines, licensing and inspection procedures, carry out trainings of inspectors on a constant basis; and it, in turn, allows to support the state quality control of medicines on due levels, considering the best world practices [8]. Taking the foregoing into consideration we analyzed the experience of the member countries of Pic/s, (or those that will enter soon into lavas of this organization) concerning the legislative definition of violations of pharmaceutical legislation.

In the United States of America the principal authority for observance of requirements of the pharmaceutical legislation is Food and Drug Administration (FDA). The activity of FDA is performed in the form of cooperation with each state separately. At the same time considering that the majority of cases of such offenses as drug falsification has the signs of the interregional activity when counterfeit medicines move from one state to another becoming the national problem such activity receives the federal level [10].

At the legislative level violations of the law about medicines in the USA are provided by section 21 of the Code of the USA, which contains standards of the basic law of the country concerning the drug control, – the Federal Law on food, drugs and cosmetics (FDCA) [9].

In Great Britain the basic standard legal act concerning the pharmaceutical activity is the Law on drugs from 1968, which consists of eight parts by the particular directions of the pharmaceutical activity: licensing, the sales order of particular types of medicines, the order of functioning of pharmacy institutions and so forth [6]. This Law also defined bodies exercising control functions in the pharmaceutical sphere and their powers.

The authorized government body in the pharmaceutical sphere of Great Britain is Medicines and Healthcare products Regulatory Agency – MHRA [7]. Its main task is ensuring observance of the international standards in the territory of the country by license, registration, inspection procedures and supervision of the pharmaceutical

market. MHRA acts also as law enforcement agency because it is authorized by the Law on drugs to investigate and finish to court the facts of violation of the pharmaceutical legislation. For this purpose in the structure of MHRA there is a special subdivision – the Inspection on enforcement of the Division of Enforcement and standards.

Materials and Methods

During our research we used a legallistic method for the analysis of the contents of standardly legal acts, which norms establish administrative responsibility for an offense in the pharmaceutical sphere.

Results and Discussion

Representatives of the science of the Administrative Law Unit report that the area of the offenses (crimes and violations) may be economic, military, traffic, tax, customs, etc. [4]. In our opinion, the pharmaceutical sphere is not the exception. There are almost all types of legal responsibility (criminal, administrative, disciplinary, civil law) used for guilty proprietors of the pharmaceutical activities. However, the classification of offenses as the grounds for any kind of liability in this case requires further study.

Most of scientists who are representatives of the theory of law science define the offense as a socially harmful, unlawful, tartaric force of a capable entity that entails legal liability [3]. The main features are the act of the offense conduct, which is reflected in specific actions or omissions, illegality, social harm, the guilt of a person, legal responsibility.

Let us analyze the above-mentioned features for definition of pharmaceutical offenses.

S.S.Alekseev states that the offense is always an act of behaviour that is reflected in the actions or inaction. Conceptions, feelings, political and religious views that do not have their expression in action, cannot be considered offences [1]. For example, Art. 54 Law of Ukraine "Fundamentals of legislation of Ukraine about health" defines the procedure for providing the citizens with medicines, according to which the pharmacy and healthcare institutions can dispense medicines and immunobiological drugs approved for use by the Ministry of Public Health of Ukraine and are responsible for ensuring their proper storage and sale. Thus, selling for citizens medicines that do not comply with the set norms is an act of behaviour – the active actions of particular pharmacists breaking the regulations and there is the responsibility for them according to Art. 168^1 of the Code of Ukraine on Administrative Offences [2]. Article 15 of the Law of Ukraine "About Medicines" provides the right for state bodies of drug control to give obligatory orders to eliminate violations during production and transportation, storage and distribution of medicines. Accordingly, non-performance of these orders by authorized persons of pharmacies will be inactivity or abstention from actions required by law.

Wrongfulness as a sign of offense does not correspond to the law and commits contrary to the law. Offences in the pharmaceutical sector may be due to the violation of legal prohibitions (e.g. Art. 21 of the Law of Ukraine "About Medicines" prohibits selling of expired drugs for citizens) or legal obligations (e.g. paragraph 11 of the Procedure for state quality control of medicinal products imported to Ukraine, approved by the Cabinet of Ministers of Ukraine from 14.09.2005, obliges the pharmaceutical activities proprietors to provide access of state bodies of control for inspection, cargo and sampling in the amount required for analysis).

Social insecurity of pharmaceutical legislation violations is always very high because the subject of any legal relations here is health of citizens. It is unimportant when these relations arise, more importantly, to provide medicines of good quality for citizens.

The pharmaceutical industry appears as a complex system, it is a set of interconnected group of relations arranged in a definite sequence. Each of such groups of relations (preclinical and clinical trials, drug certification procedure, the order for import into the territory of Ukraine, wholesale and retail sale of pharmaceutical products, etc.) is regulated by particular (special) standard acts and by general standard acts (e.g. Law of Ukraine "About Medicines"). Thus, the offense at any stage of the pharmaceutical activity may cause a threat to the health and lives of citizens.

It is possible to say that the level of social dangerous offenses in the pharmaceutical sector is very high because of many known examples of using substandard or even counterfeit medicines and the extents in different countries (for example, according to Western experts, counterfeit of antimalarial medicines is the cause of 200 deaths annually [5]).

Guilt of a person in offense is obligatory feature. It is not every unlawful behaviour is an offense because it must be carried out under the influence of free will and mind of the person to be conscious, and therefore – guilty. The offense can take place only in the commission by a competent person.

The offense in the pharmaceutical sector (as in any other sectors) is socially dangerous, the state cannot stand outside. Therefore, another common feature of these offenses is that they serve the grounds of legal liability. As we have already noted, offenders of legislation in the pharmaceutical sector brought by state to the various types of liability depending on the degree of social danger and the subjects such as criminal, administrative, disciplinary.

Thus, the offense in the pharmaceutical sector is guilty, intended or careless acts or omissions of delict persons involved in creating, registration, production, quality control, transportation and sale of medicines that violate the legal rules regulating the circulation of medicines, and by law the responsibility is provided for them.

The purpose of this article is an attempt of structural analysis and classification of offenses in the pharmaceutical sector taking into account the criteria accepted in legal scholarship.

In the law theory offenses (delicts) are divided into crimes and misdemeanors according to the degree of social danger and legal registration.

Speaking of crimes in the pharmaceutical field first should be noted the fact that pharmacists can be the subject

of the offense provided by such articles of the Criminal Code as "Improper implementation of professional duties, which has caused HIV infection or any other incurable contagious disease for a person" (art. 131); "Improper implementation of professional duties by a medical or pharmaceutical worker" (art. 140), and a number of crimes that infringe on the established order of narcotic drugs circulation and are specified by Chapter XIII of the Criminal Code "Offenses related to narcotic drugs, psychotropic substances, their analogues or precursors and other crimes against human health", "Illegal prescription for purchasing drugs or psychotropic substances" (art. 319) or "The violation of rules about circulation of narcotic drugs, psychotropic substances, their analogues or precursors" (art. 320).

The State Administration of Ukraine on Medicinal Products is the central authority of administrative power, which is formed for implementation of the state policy in the field of quality and safety control of medicines, including immunobiological medicines, medical equipment and medical products that are in circulation and / or used in the health sector, approved for selling in pharmacies and their structural subdivisions, as well as licensing of drug manufacturing, wholesale and retail sale of medicines.

Thus, the second group of crimes in the pharmaceutical field are socially dangerous acts associated with the duties of employees of the State Drug Service of Ukraine. In this group of crimes especially noted crimes are contained in Chapter XVII of the Criminal Code of Ukraine "Crime in the area of implementation" namely, "the abuse of power or position" (art. 364), "the abuse of power or authority" (art. 365), "forgery" (art. 366), "negligence" (art. 367), "getting a bribe" (art. 368), "giving a bribe" (art. 369), "provoking a bribe" (art. 370).

Describing administrative offenses in the pharmaceutical field we consider that due to jurisdiction of cases they may be conditionally divided into three groups:

1. Cases, which consideration relates to the authority of the government drug quality control (Art.244-8 Codex of Ukraine on Administrative Offences), namely: violation of the established order about taking, processing, storage, sale and use of the donor blood and (or) its components and preparations (art. 45^1); production and sale of products that do not correspond to standard requirements (art. 167); appearance of non-standard products on sale (art. 168), works and services giving to the citizens-consumers that do not correspond to the standards, rules and regulations (art. 168^1); giving documentation that does not correspond to the standards to the customer or manufacture (art. 169), not keeping to standards during transportation, storage and use of products (art. 170), the failure of legitimate claims by officials of the State Drugs Quality Control bodies (art. 188^{1o}).

2. Cases, which consideration relates to the authority of the executive power in the field of consumer protection (Art. 244-4 Codex of Ukraine on Administrative Offences), namely: violations of trade and service for trade workers, catering and services, individuals engaged in the entrepreneurial activity (art. 155) deception of a buyer or a customer (art. 155^2); violation of the law on consumer protection (art. 156^1).

3. Cases, which consideration relates to the authority of district, town or city district courts (judges) Art.221 Codex of Ukraine on Administrative Offences, namely: violation of the right on the intellectual property object (art. 51^2); disorder of payments (art. 155^1); illegal trading activities (art. 160^2); violation of economic activities (art. 164) unfair competition (art. 164^3).

It should also be noted that in addition to the *Code of Ukraine on Administrative Offences* the question of responsibility for offenses in the pharmaceutical field are also provided in some laws of Ukraine, such as the Law "On Advertising". The order of drug advertising is defined in Article 21, and Article 27 provides the liability of violators of legislation on advertising, particularly in the form of five times value of widespread advertising for advertisers [10].

The current administrative legislation does not contain specific provisions that would establish liability for committing administrative offenses directly in the pharmaceutical field by persons who are endowed with powers. The analysis of legislation on administrative responsibility leads us to conclusion that the administrative offenses may include acts under the articles of the *Code of Ukraine on Administrative Offences* "discrimination of entrepreneurs by administrative and control powers" (art. 166-3), "violation of legislation on licensing certain types of activities" (art. 166-12), "violation of the right on information" (art. 212-3).

CONCLUSIONS

We believe that these features of crime in the pharmaceutical field will provide details of offenses and personalize their subjects, and it will be able to use more effectively legal measures and sanctions to offenders and more effectively counteract violations of pharmaceutical legislation.

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ОКРЕМІ ОЗНАКИ КЛАСИФІКАЦІЇ ПРАВОПОРУШЕНЬ, ЩО СКОЮЮТЬСЯ У ФАРМАЦЕВТИЧНІЙ СФЕРІ УКРАЇНИ

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Ключові слова: *правопорушення; злочини; адміністративна відповідальність; фармацевтична сфера*

Розглядаються питання класифікації правопорушень у фармацевтичній сфері з урахуванням загальноприйнятих у правовій науці критеріїв. Виділені основні групи злочинів та адміністративних порушень у фармацевтичному секторі охорони здоров'я. Правовідносини, що виникають у фармацевтичній сфері потребують постійного захисту з боку державних органів шляхом здійснення заходів, спрямованих на попередження та виявлення правопорушень фармацевтичного законодавства, а також притягнення винних осіб до відповідальності. Під час дослідження нами використовувався формально-юридичний метод для аналізу змісту нормативно-правових актів, норми яких встановлюють адміністративну відповідальність за правопорушення у фармацевтичній сфері. Характеризуючи адміністративні порушення у фармацевтичній сфері, вважаємо, що за критерієм підвідомчості справ їх умовно можна поділити на три групи: 1. Справи, розгляд яких відноситься до повноважень органів державного контролю якості лікарських засобів (ст. 244-8 КУпАП). 2. Справи, розгляд яких відноситься до повноважень органів виконавчої влади у сфері захисту прав споживачів (ст. 244-4 КУпАП). 3. Справи, розгляд яких відноситься до повноважень районних, районних у містах, міських чи міськрайонних судів (суддів) (ст. 221 КУпАП). Вважаємо, що зазначені ознаки правопорушень у фармацевтичній сфері дозволять конкретизувати склади правопорушень та персоніфікувати їх суб'єктів, що дасть можливість більш дієво застосовувати заходи юридичної відповідальності до правопорушників та більш ефективно протидіяти порушенням фармацевтичного законодавства.

ОТДЕЛЬНЫЕ ПРИЗНАКИ КЛАССИФИКАЦИИ ПРАВОНАРУШЕНИЙ, СОВЕРШАЕМЫХ В ФАРМАЦЕВТИЧЕСКОЙ СФЕРЕ УКРАИНЫ

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Ключевые слова: правонарушение; преступление; административная ответственность; фармацевтическая сфера

Рассматриваются вопросы классификации правонарушений в фармацевтической сфере с учетом общепринятых в правовой науке критериев. Выделены основные группы административных проступков в фармацевтическом секторе здравоохранения. Правоотношения, возникающие в фармацевтической сфере, нуждаются в постоянной защите со стороны государственных органов путем осуществления мероприятий, направленных на предупреждение и выявление правонарушений фармацевтического законодательства, а также привлечение виновных лиц к ответственности. В процессе подготовки статьи нами использовался формально-юридический метод для анализа содержания нормативно-правовых актов, которые устанавливают административную ответственность за правонарушение в фармацевтической сфере. Характеризуя административные проступки в фармацевтической сфере, считаем, что по критерию подведомственности дел их условно можно поделить на три группы: 1. Дела, рассмотрение которых относится к полномочиям органов государственного контроля качества лекарственных средств (ст. 244-8 КУАП). 2. Дела, рассмотрение которых относится к полномочиям органов исполнительной власти в сфере защиты прав потребителей (ст. 244-4 КУАП). 3. Дела, рассмотрение которых относится к полномочиям районных, районных в городах, городских или горрайонных судов (судей) (ст. 221 КУАП). Считаем, что указанные признаки правонарушений в фармацевтической сфере позволят конкретизировать составы правонарушений и персонифицировать их субъектов, что даст возможность более действенно применять меры юридической ответственности к правонарушителям и более эффективно противодействовать нарушениям фармацевтического законодательства.