ORGANIZATIONAL AND LEGAL REGULATION PROCEDURE FOR CIRCULATION OF EXTEMPORAL MEDICINES BASED ON PHARMACEUTICAL LAW

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Introduction

Medicines made in the pharmacies by the individual doctor's prescription from the point of view of biopharmaceuticals are much more effective than similar drugs manufactured in industrial conditions [1]. Therefore, extemporal medicines are still relevant, especially for inpatient facilities, since the existing range of ready-made drugs can not fully meet the needs of patients, since there are such drugs that are not produced by pharmaceutical companies at all for various reasons [2, 3]. An example of this can be the drugs for children and newborns [4, 5].

Statement of the problem in general, relevance of the topic and its connection with important scientific or practical issues

Production of drugs in pharmacies has many advantages [6], so that patients can receive extemporal medicines to the needs of a particular patient, its diagnosis, age, individual sensitivity and intolerance to individual components. However, the production of extemporal medicines requires the presence of a relevant production base and qualified staff at the pharmacy [7, 8].

Analysis of recent researches and publications in which the solution to this problem initiated and on which the author relies

Previously, the authors developed an organizational and legal procedure for the circulation of drugs: prescription and OTC drugs [2], combined drug and precursor drugs [5], as well as licensing activities of drugs' circulation [8], the definition of nomenclature and legal [5], the classification and legal groups, the control regime, the scientific information and analytical program "NIAP" regarding the qualification of the control regime for medicines of various classification and normative groups [7].

Selection of previously unsettled parts of the general problem, which is devoted to the article

Today, in Ukraine, there is no clear-cut organizational and legal procedure of the circulation of extemporal medicines; therefore, issues related to its development, especially at the stage of quality control, remain relevant. Ensuring the quality of extemporal medicines involves meeting the relevant requirements for workers and requiring highly skilled professional knowledge, skills and abilities. As the profession of pharmacist is becoming more and more important today, the issue of improving of the professionalism and competence of pharmacists, in particular the definition of the professional status of an authorized person at the stage of quality control of extemporal medicines in their circulation in healthcare establishments remains a topical issue.

Formulating the goals (tasks) of the article

The purpose of the study was to work out the organizational and legal procedure for regulating of the circulation of extemporal medicines by developing an algorithm for the definition of a normative and legal act, which used by an authorized person in the event of a conflict of law in the pharmaceutical legislation.

Presentation of the main research material (methods and objects) with the justification of the results

The materials of the study were legal acts of Ukraine: Laws of Ukraine (3), Decrees of the Cabinet of Ministers of Ukraine (3), Orders of the Ministry of Healthcare of Ukraine (5). *The research methods* were legal, documentary and comparative analyzes.

Results of the research and their discussion. Based on the conducted research, an organization and legal procedure was developed for regulating of the circulation of extemporal medicines and proposed an algorithm for the determination of the normative and legal act, which used by an authorized person at the stage of quality control of extemporal medicines (Figure 1).

The proposed algorithm worked out in determining the status of an authorized person in the healthcare instituion, involved in the production of the extemporal medicines (pharmacies, hospitals). In case of inconsistency between the current normative acts of Ukraine, their contradiction with the same subject of regulation, as well as the contradiction between formally operating norms of law adopted on the same issue, which in the legal sphere is defined as a conflict of law, then a question arises on the necessity of choosing a normative act used by an authorized person which apply to a specific case. Important to recall that in Ukraine, a quality system has been introduced and functioning, developed in accordance with the requirements of the international pharmaceutical inspection cooperation system (PIC/S); WHO; the national standard DSTU ISO 9001:2009 licensing of the activities of the circulation of medicines [8, 9]. A compulsory component of the quality system is the presence of an authorized person in the healthcare institutions. Particular importance is the position of an authorized person healthcare instituions of private property, in staffing lists who do not have the position of pharmacist-analyst. In such healthcare instituions, the extemporal medicines circulation at the quality control stage must perform with the help of an authorized person.

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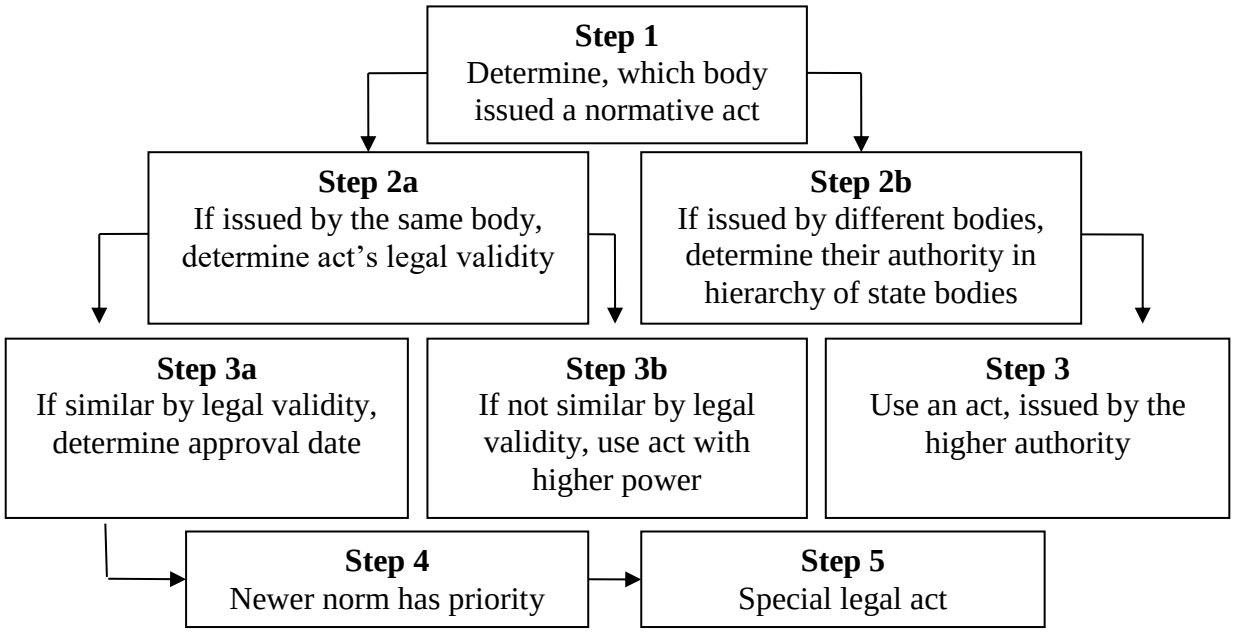

Figure 1 – Algorithm of the definition of a normative and legal act, which used in the accidence of a conflict of law with respect to the regulation of the circulation of extemporal medicines

It should be noted that in the EU countries, the designation of an authorized person is a prerequisite for obtaining a license for the circulation of medicines (stages: the manufacture of medicines, the production of extemporal medicines), and the change in the personal composition of an authorized person is impossible without prior agreement with the licensing authority. Thus, in accordance with the requirements of the GMP, an authorized person appointed from the management of the healthcare institution and is responsible for the organization and operation of the quality system, granting permission for the implementation of each series of drugs, participates in the development of quality control guidelines, etc. [10].

Guided by the developed algorithm, we will analyze the professional status of an authorized person at the stage of quality control of extemporal medicines in their circulation in the healthcare institutions of private ownership. Established that this issue regulated by several normative documents. Paragraph 5.1 of the *order of the Ministry of Healthcare of Ukraine dated 17.10.2012 No. 812 "On approval of the Rules for production (manufacturing) and quality control of the medicines in pharmacies"* in relation to the qualification requirements for an authorized person specifies next. Pharmacies, involved in production (manufacturing) of medicines must have a staff member who have an appropriate special education and meet the same qualification requirements. Paragraph 5.7 determines that "Pharmacist-analyst carries out systematic supervision of the technological process of production (manufacturing) of medicines and instructs persons who participate in it". At the same time, paragraph 5.6 of this order states that "An authorized person must possess all types of internal pharmacy quality control of produced (manufactured) medicines and in the matter of absence of pharmacist-analyst to ensure its implementation". Consequently, there are no qualifying requirements for an authorized person in this order.

Subsequently, while studying the *order of the Ministry of Healthcare of Ukraine dated 09.29.2014 No. 677 "On approval of the procedure for the control of the quality of medicines in the wholesale and retail trade"* regarding the qualification requirements for an authorized person, we established the following. An authorized person must be a specialist with a complete higher pharmaceutical education and the work experience in the specialty of at least 2 years. Additionally, the subject of economic activity assigns responsibilities for the effective management of the quality system of medicines in their wholesale and retail sales, the conduct of input quality control of the drugs, in particular extemporal medicines to an authorized person [11, 12].

Performing duties of an authorized person responsible for the effective management of the quality system of the medicines in healthcare institutions, located in the countryside, can be relied upon a person with a pharmaceutical education who has acquired an educational qualification level of a specialist junior specialist, bachelor. An authorized person's duties in rural areas can be relied upon specialists without professional experience [13].

At the same time, in the *order of the Ministry of Healthcare of Ukraine dated 16.12.2003 No. 584 "On approval of the rules for the storage and conducting of quality control of medicines healthcare institutions"*, an authorized person defined as "specialist (head/senior nurse, pharmacist/pharmacy technician), appointed by the order of the head of the healthcare institution, which assigned the function of holding responsibility for the quality of the medicines that come to the healthcare institution"[14].

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The main purpose of an authorized person's activity is to provide an adequate level of quality of medicines from the moment of their actual receipt, during the storage and their medical application. Such actions are aimed at preventing the use of counterfeit, poor-quality and unregistered medicines [9, 10]. On this issue analyzed the provisions of the *order of the Ministry of Healthcare of Ukraine dated 31.10.2011 No. 723 "On approval of licensing conditions for conducting economic activities for the production of medicines, wholesale and retail trade of medicines"* (in the edition of the order of the Ministry of Healthcare of Ukraine dated 22.12.2014 No. 990). Indicated there, that an authorized person is a "person who has a diploma in the field of pharmaceutical education issued by educational institutions of the III-IV accreditation levels and a certificate of assignment (confirmation) of the rank of a pharmacy specialist or certified in this specialty with an assignment (confirmation) of the qualification category and has experience of work in the specialty "Pharmacy" at least 2 years (quality assurance of medicines in the pharmacy located in a village, settlement, urban-type settlement can be relied on a person holding a diploma of the pharmaceutical education issued by educational institutions of the I- II levels of accreditation, or a person who has received a bachelor's degree in educational institutions of the III-IV accreditation levels without experience in the specialty "Pharmacy"), to which assigned responsibilities for the functioning of the system of quality assurance of medicines in their wholesale and retail trade».

Also, in the above-mentioned order specified the particularities of the professional status of an authorized person in healthcare institutions who engaged in the *industrial production* of medicines this should be "a specialist with a complete higher pharmaceutical, chemical, biological or biotechnological education and experience in the profession of at least 2 years in the field of production, quality control, or the creation of a medicines who is entrusted with the responsibilities for the functioning of the system of quality assurance of medicines in their production and granting a permit for the issuance (realization) of the medicines". Consequently, the last document specifies the qualification requirements for a specialist, which can hold the functions of an authorized person.

With the help of the developed algorithm (Fig. 1), we will select a normative and legal act, which guides in determining of the professional status of an authorized person. First, determine which authority issued the normative act (Step 1). The aforementioned normative documents issued by the Ministry of Healthcare of Ukraine, that is, by the same body. Next, we establish the legal validity of the researched documents (Step 2a): these are orders, that is, they are equal to each other by legal force. The next step is to clarify the timing of the adoption of these orders (Step 3a). We use the rule (Step 4) that the priority is the normative document (Step 5) issued later (even if the act previously adopted has not lost its validity). Important to note that such a disagreement might arise from the fact that the adoption of the latest norm not always accompanied by the abolition of previous rules on the same issue.

With the help of the developed algorithm established that when determining the professional status of an authorized person, which has a diploma in pharmaceutical education of educational institutions of the III-IV levels of accreditation and a certificate of assignment (confirmation) of the rank of specialist pharmacist or certified in this specialty with the assignment (confirmation) of the qualification category and has experience of work on the specialty "Pharmacy" not less than 2 years (quality assurance of medicines in a pharmacy located in a village, settlement, urban-type settlement, can rely on a person holding a diploma ro pharmaceutical education of educational institutions of the I-II levels of accreditation, or a person who has received a bachelor's degree in educational institutions of III-IV accreditation levels, without experience in the specialty "Pharmacy"), who is entrusted with the responsibilities for the operation of the quality assurance system of extemporal medicines with their wholesale and retail trade", necessary to follow the provisions of the *order of the Ministry of Healthcare of Ukraine dated 22.12.2014 No. 990 "On amendments to certain orders of the Ministry of Healthcare of Ukraine"*.

As can be seen from Fig. 1, in the event of a mismatch between acts issued by the same body, but having different legal force, an act of higher legal force is applied (Step 3b). For example, in case of divergence of the norms of the law and the Constitution of Ukraine adopted by the Verkhovna Rada of Ukraine, the conflict is resolved in favor of the Constitution, which has the highest legal force. In the event of a difference between the acts adopted by the various bodies in place in the hierarchical structure (Step 2b) higher and lower, an act adopted by the supreme body as having greater legal force is applied (Step 3). In addition, in case of divergence between general and special legal acts, the advantage given to a special one, if not abolished by issued later general act [15].

As an example, let us consider the issue of determining the validity of the license for business in the pharmaceutical industry. Thus, an Article 13 (paragraph 12) of the Law of Ukraine "On licensing of types of economic activities" states, "The license is issued for an unlimited period". Article 7 (paragraph 10) of the same Law stipulates that licensed production of medicines, wholesale and retail trade in medicines, and the import of medicines (except for active pharmaceutical ingredients) are subject to licensing. The licensing procedure is carried out taking into account the specifics defined by the *Law of Ukraine "On medicines"*. At the same time, in paragraph 22 of this article noted the activity of cultivating plants included in Table I of the List of narcotic drugs, psychotropic substances and precursors, approved by the Cabinet of Ministers of Ukraine, the development, production, manufacture, storage, transportation, purchase, sale (release), the importation into the territory of Ukraine, export from the territory of Ukraine, the use, destruction of narcotic drugs, psychotropic substances and precursors included in the above List, carried out taking into account the

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particularities defined by the *Law of Ukraine "On narcotic drugs, psychotropic substances and precursors"*. Consequently, while determining the term of the license for the circulation of narcotic drugs, psychotropic substances and precursors, the special legal act, that is, the Law of Ukraine "On narcotic drugs, psychotropic substances and precursors", where Article 8 states that "The license for the conduct of activity in the circulation of narcotic drugs, psychotropic substances and precursors is issued for five years".

Conclusions from the conducted research and prospects of further development of this direction

On the principles of pharmaceutical law, developed an organizational and legal procedure to regulate the circulation of the extemporal medicines. An algorithm proposed for the definition of normative and legal act, which used in the practical activities of an authorized person. Reviewed the professional status of an authorized person at the stage of quality control of extemporal medicines on the stage of their circulation in private healthcare institutions. Determined the the main objective of an authorized person activity in healthcare institutions.

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Introduction. The paper studied the situation regarding the production of medicines in pharmacies. Established that the presence of the pharmacy manufacture of medicines, patients entitled to receive medicines made to the needs of individuals. Goal – to study the organizational and legal procedure of regulation of extemporal medicines by developing of the algorithm for determining the legal act used in the event of conflict based on the law pharmaceutical law. **Materials and methods.** The materials of the study were legal acts of Ukraine: Laws of Ukraine, Decrees of the Cabinet of Ministers of Ukraine, Orders of the Ministry of Healthcare of Ukraine. The research methods were

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legal, documentary and comparative analyzes. **Results and discussion.** However, production of extemporaneous preparations in the pharmacy requires a production base and the appropriate staff. Therefore, the authors based on pharmaceutical law proposed organizational and legal procedure regarding the regulation of extemporaneous preparations by developing the algorithm for determining the legal act which should follow in the event of conflicts concerning the law. **Conclusions.** Based on pharmaceutical law held organizational and legal procedure for the regulation of circulation of extemporal medicines. Proposed the algorithm for determining of the legal act used in the practice of pharmacy professionals. Considered the professional status of an authorized person on the stage of quality control of extemporal medicines in their treatment in healthcare institutions of private property.

Keywords: the legal procedure, circulation, extemporal medicines, pharmaceutical law.

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