## LEGAL REGULATION OF PROCUREMENT OF NARCOTIC DRUGS IN UKRAINE WITH INVOLVEMENT OF INTERNATIONAL SPECIALIZED ORGANIZATIONS

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Procurement of narcotic drugs with the involvement of specialized organizations is a component of the successful functioning of the country's health system. The right to free medical care in state and municipal health institutions is enshrined in the Constitution of Ukraine (Part 3, Article 49) [7] and includes, in particular, the provision of patient needs for narcotic drugs through procurement by for budgetary funds. The total allocation of the state budget allocated to the Ministry of Health for the centralized purchase of medicines for the implementation of national health programs increased from 40,989 UAH in 2015 to 5,949.0 million UAH in 2017 [5, p.4]. So, in 2016 about 13 million UAH (about 500 thousand US dollars) were allocated from the State Budget of Ukraine for the purchase of drugs for substitution maintenance therapy (hereinafter - SMT) [18]. © *GMN* 

It should be noted that the problems of the legal regulation of public procurement exist in all countries, regardless of the level of their development, and participants in such purchases face difficulties at virtually all stages of the contract process, at all levels of its implementation [32, p. 35]. Also topical problems are corruption [33], conflict of interests (in practice: civil servants are still chosen as winners of tenders for themselves with the help of third parties) [31, p. 21-26]. According to the calculations of the European Commission, member countries annually lose about 163 billion US dollars due to corruption in the procurement sphere [33]. With the aim of eliminating corruption schemes in the conduct of tender purchases in this area, the purchase of medical products in Ukraine has been transferred to

international organizations of the UN system and other organizations and funds (paragraph 8) [29].

We also note the small number of scientific works devoted to the problems of legal regulation of the procurement of narcotic drugs with the involvement of international specialized organizations, which is the reason for the relevance of this study. The system of public procurement requires further legal certainty and improvement, increasing requirements for narcotic drugs as a subject of procurement, accelerating the procurement procedure, developing and enforcing economic competition in this area, proper fulfillment of contract obligations, establishing a mechanism for the permanent provision of these drugs to patients and a number of other critical activities.

This study is based on an interdisciplinary approach to the analysis of the problem of the legal regulation of the procurement of narcotic drugs for the SMT program with the involvement of international specialized organizations using comparative legal, dialectical and systemic methods.

Before considering aspects of the legal regulation of the procurement of narcotic drugs with the involvement of international specialized organizations, definitions should be given for understanding of the terms "state procurement" and "public procurement". In the scientific literature the term "state procurement" [9, p. 23] can be used as well as "public procurement" [4, p. 30]. There is an opinion that the term "state procurement" should be replaced with "public procurement" [9, p. 72], and another point of view is they are opposed: state procurement is considered as a partial, public procurement - as a whole [4, p. 35]. It should be noted that after the reform of the sphere of public procurement (we are talking about the Law of Ukraine "On the Implementation of Public Procurement", which has lost its force from 01.08.2016), the term "state procurement" has dropped out of circulation at the legislative level. Since August 2016, the term "public procurement" is intended as the acquisition by a customer of goods, works and services in accordance with the procedure established by the Law of Ukraine "On Public Procurement" (clause 20, Article 1); the preamble of this Law provides that it establishes legal and economic principles of the procurement of goods, works and services to ensure the needs of the state and territorial community [28].

In international legal acts it is said: (1) the term "procurement" is defined as the acquisition by any means of goods (works) and services (Article 2) [30]; (2) "State purchases of goods" are purchases by state agencies of goods purchased for the state needs which are not intended for commercial resale or for using in the production of goods for commercial sale [1], (3) state procurement is one of the forms of using only those public funds which are directed (intended) for the acquisition of works, goods or services by means of the award of a public contract (clause 4) [3]. In some national regulations, the term "public procurement" (clause 6-1, clause 1) [12] and "state procurement" (clause 3.4) are used [14,15].

State purchases of medicines in legal literature are defined as the aggregate of legal relations between participants in state procurement with respect to the purchase of medicinal products in accordance with the procedure established by law to meet the needs of the state and the territorial community for the necessary medicines to continue saving lives [11, p. 90].

In the legal regulation of procurement of narcotic drugs for budgetary funds, the Constitution of Ukraine has the highest legal force. The Constitution of Ukraine stipulates the following: (1) freedom of entrepreneurial activity not prohibited by law; (2) ensuring the state's protection of competition in business; (3) preventing unjustified restriction of competition and unfair competition (Article 42); (4) determining any state expenses for public needs, size and target direction of these expenditures exclusively by the Law on the State Budget of Ukraine (Article 95), etc. These norms are of a general nature and apply to all purchases of goods through the budgetary funds, regardless of the type of procurement subject.

In the Law there are norms which establish the legal basis for procurement of narcotic drugs. The right to protect health is enshrined in the Constitution of Ukraine, the state creates conditions for the effective and affordable medical care for all citizens. In the state and municipal health institutions, medical care is provided free of charge (part 3 of article 49). Health care in Ukraine is provided by the state funding of conforming socio-economic, health and health-prevention programs (Article 49) [7], such financing includes, inter alia, the purchase of narcotic drugs for the SMT program with the involvement of international specialized organizations, and consequently, they are one of the ways to ensure the constitutional right of every person to health.

In the hierarchy of legislation, in particular in the area of procurement of medicines, the following international legal acts are approved by the Verkhovna Rada of Ukraine, which are binding on the mandatory requirements, such as the UNCIT-RAL Model Law on Public Security [30]; General Agreement on Tariffs and Trade [1], Directive 2014/24/EC of the European Parliament and the Council on Public Procurement [3]. It should be noted that Ukraine has ratified the Single Convention on Narcotic Drugs of 1961, the UN Convention on Psychotropic Substances of 1971 and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 is obliged to fulfill their provisions, primarily providing drugs for the treatment of drug dependent patients for medical reasons at the expense of public funds.

In March 2015, the Verkhovna Rada of Ukraine introduced the need for the implementation during 2015 - 2019 of public procurement of medicines with the involvement of international specialized organizations [16] at the legislative level. It should be noted that during 9 years of operation the SMT program in Ukraine is implemented through grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria, and only since 2016 it is planned to purchase narcotic drugs for the SMT program with the involvement of international specialized organizations [8].

Important is the fact that the Law of Ukraine «On Public Procurements» does not regulate legal relations relating to international specialized organizations as subjects for the purchase of narcotic drugs. International specialized organizations provide governments and / or central government authorities with services for the organization and conduct of procurement procedures for medicines and related services, on the basis of relevant agreements and in accordance with the internal rules and procedures of such organizations [28]. In fact, the activities of international specialized organizations for the procurement of narcotic drugs are derived from legal relations that provide for the needs of the state and the territorial community. The Law of Ukraine «On Public Procurements», enumerates a list of international specialized organizations: specialized funds, organizations and mechanisms of the United Nations, International Dispensary Association, Crown Agents, Global Drug Facility, Partnership for Supply Chain Management, NATO Support and Procurement Agency 1) [28]. Thus, the British company Crown Agents was designated by the Ministry of Health of Ukraine to carry out procurement of drugs for the SMT program [8].

Requirements for narcotic drugs as a subject of procurement are determined in accordance with the provisions of the Laws of Ukraine "Fundamentals of Ukrainian legislation on health" [10], "On medicines" [26], "On narcotic drugs, psychotropic substances and precursors" [27], their regulations affect the planning of procurement of narcotic drugs and are calculated when determining the amount of expenditure in the state budget of Ukraine for the relevant year.

With regard to narcotic drugs as a subject of procurement, it should be noted that the concept of "medicine", the procedure for its use, production, sale are determined by the Law of Ukraine "On Medicines" [26]. Article 2 of this Law determines that narcotic drugs are medicines classified as narcotic according to the law. The Law of Ukraine "On Narcotic Drugs, Psychotropic Substances and Precursors" defines the term "narcotic drugs", "psychotropic substances" and precursors (Article 1). In the medical practice, narcotic drugs, psychotropic substances included in tables II and III of the List of narcotic drugs, psychotropic substances and precursors, and precursors included in table IV of this list can be used. The legal relations connected with the circulation of narcotic drugs, psychotropic substances included in Tables II and III of the List and precursors included in Tables IV of the List, which are permitted for use in medical practice are covered by the legislation on medicines in the part not contradicting this Law (art. 21) [27].

In the provisions of the Law of Ukraine "On Medicines" legal features of medicinal products affecting their specificity as the subject of procurement are fixed, and, in our opinion, they should be taken into account when forming requirements for them as the subject of procurement. This refers to Article 9 of the Law, which stipulates that medicinal products are allowed for use in Ukraine after their state registration; In accordance with Articles 10 and 19 of the Law, the production of medicines, their wholesale trade, retail trade in the territory of Ukraine is carried out by enterprises, institutions, organizations and individuals-entrepreneurs on the basis of a license [27], licensing conditions - availability of qualified personnel, a certain material and technical base, the appropriate technological requirements in accordance with the terms of the license. The sale (release) of narcotic drugs, psychotropic substances and precursors registered as medicinal products is carried out in accordance with the Law of Ukraine "On Medicines" and taking into account the requirements specified by the Ministry of Health of Ukraine. From our point of view, the term "narcotic drugs" and "psychotropic substances" and "drugs containing narcotic drugs, psychotropic substances and precursors" need to be distinguished at the legislative level, by drafting the Law of Ukraine on Amendments to the Laws of Ukraine "On Medicinal means", "On narcotic drugs, psychotropic substances and precursors" that certain subordinate regulations and legal acts.

Also, state targeted programs in the field of health play a significant role for the procurement of narcotic drugs with the involvement of international specialized organizations, they are approved by the laws of Ukraine, in particular, on the approval of the National Program for HIV Prevention, Treatment, Care and Support for People with HIV and AIDS 2009 - 2013 [19], which provides for increased access of injecting drug users, especially those infected with HIV, to SMT programs.

Some subordinate regulatory legal acts occupy a separate place in the hierarchy of legislation regulating relations in the procurement of narcotic drugs with the involvement of international specialized organizations. Resolution of the Cabinet of Ministers of Ukraine № 622 of July 22, 2015 establishes the criteria for the selection of international specialized organizations for the pur-

chase of medicinal products, including those containing narcotic drugs or psychotropic substances and precursors: (1) technical and professional ability to realize tasks for the procurement and supply of medicines; (2) the possibility of purchasing and supplying the necessary quantity of goods of appropriate quality with an appropriate shelf life and taking into account the requirements for packaging and / or the form or size of the packaging of goods; (3) the price of services related to the procurement of goods provided by specialized organizations engaged in procurement; (4) conditions and terms of delivery of the goods; (5) terms of payment; (6) conditions of conclusion and form of purchase transactions; (7) additional delivery conditions (clause 1) [2]. It should be noted that among these data there is no such criterion as the price of the goods. In addition, the procedure and order of selecting international specialized organizations for the purchase of such funds remains unregulated.

Decree of the Cabinet of Ministers of Ukraine from 8.10.2015, № 787 approved a list of medicines purchased on the basis of agreements (contracts) on procurement with international specialized organizations. The Ministry of Health of Ukraine can increase the volume of orders for such purchases within their absolute necessity (item 2) [23]. There are: (1) a simplified mechanism for registration of medicinal products registered by the competent authority of the United States, Switzerland, Japan, Australia, Canada, and medicines registered in a centralized procedure by the competent authority of the EU; (2) the procedure for their examination and the procedure for examining materials for the manufacture of these medicines; (3) the entry of data on such medicines into the State Register of Medicines [13], (4) the prepayment for the purchase of medicines purchased in 2018 - 2019 and related services are allowed for a period not exceeding one year, and medicines purchased before of December 31, 2017 - for a period not exceeding 18 months [18]. Thus, the nomenclature of procurement of medicines purchased for public funds is formed in accordance with the above regulatory and legal acts. In addition, Ukraine has created a separate legal mechanism for the procurement of medicines, including narcotic drugs and psychotropic drugs with the involvement of international specialized organizations.

Besides this, it is worth paying attention to the regulatory legal acts of the central executive authorities in the field of procurement of narcotic drugs. In September 2016, the order of the Ministry of Health of Ukraine approved the nomenclature of drugs for the treatment of opioid dependence, which includes tableted methadone, sublingual buprenorphine tablets, oral methadone solution [22]. In the same month, the Order of the Ministry of Health of Ukraine № 1010 was developed on the methodology for calculating the requirements for SMT products at the expense of the State Budget of Ukraine [23]. Similarly, in 2016, among 9214 patients receiving SMT services, 7987 patients received tableted methadone (86.6 %), 967 tablets sublingual buprenorphine (10.4 %), 260 - oral methadone solution (2.8 %) [8, p. 40)]. So, in 2016 there was a transition for the purchase of drugs for SMT programs, 40 patients were provided with medications from the state budget and 106 patients received drugs purchased for local budgets [8, p. 41]. Thus, the majority of drug addicts received drugs for treatment for personal funds, the smaller part - at the expense of local budgets. Also in 2016, there was a practice of issuing SMT medications for self-administration by patients outside of SMT sites. As of December 31, 2016, every fifth patient received a SMT according to one of the forms of independent reception: in 17 regions of Ukraine 926 patients received SMT according to prescriptions, 328 (35.42 %) of them bought drugs at their own expense [8, p. 101].

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The protocols for the provision of medical assistance are of great importance in determining the nomenclature of narcotic drugs planned for procurement and in the formation of medical and technical requirements for them. For example, the clinical protocols for the provision of medical assistance in the specialty «Narcology», approved by the order of the Ministry of Health of Ukraine from September 21, 2009,  $N_2$  681 [20], which provide diagnostic criteria for protocols for the provision of medical care to patients with psychosomatic disorders due to the use of opioids F11.5.

Therefore, taking into account the above, we propose to divide normative and legal acts in the field of procurement of narcotic drugs into general and special ones. General legal acts are applied to all subjects of legal relations in the field of such purchases, special ones - (1) regulate the choice of drugs as a subject of procurement; (2) affect the definition of the nomenclature of narcotic drugs; (3) determine the costs in the state budget of Ukraine for these purposes and their mechanism; (4) regulate the circulation of narcotic drugs and influence the formation of medical and technical requirements for them; (5) approve state programs and activities to implement programs in the planning of procurement of narcotic drugs.

Let's consider the powers of individual entities in the procurement of narcotic drugs with the involvement of international specialized organizations. Information on the conduct of public procurement of narcotic drugs with the involvement of international specialized organizations is necessarily published on the official website of the Ministry of Health of Ukraine and the web portal of the Ministry of Economic Development and Trade of Ukraine (item 3). Maintenance of narcotic drugs throughout the territory of Ukraine is carried out by state enterprises of the Ministry of Health of Ukraine on the basis of the relevant agreement (item 4) [2]. Such an enterprise for the purchase of narcotic drugs for SMT programs belongs to Ukrmedpostach. This organization must have a license, equipment, each delivery of narcotic drugs requires special storage with the provision of electronic means of protection [27]. Crown Agents buy narcotic drugs from manufacturers or distributors of narcotic drugs.

Attention should be paid to monitoring of the use of budgetary funds in the procurement of narcotic drugs with the involvement of international specialized organizations. Thus, the Ministry of Health of Ukraine ensures effective and targeted use of budgetary funds. The Ministry of Health of Ukraine, as the chief administrator of budgetary funds, is responsible for drawing up a budget request (item 8) [24], including medicines for the program of SMT. Obtaining of narcotic drugs by patients is possible free of charge at the expense of the state budget (but only those patients who are on official records and match the criteria for inclusion in SMT programs) [34, p. 163]. The decision on the onset of SMT, the drug for its implementation and its dose is taken by a drug specialist on the basis of: (1) a diagnosis of dependence on opioids according to ICD-10, (2) compliance with criteria for the prescription of SMT and (3) the availability of an identity document. The patient must sign consent to receive SMT medications in the form of an «Information letter on substitution maintenance therapy with buprenorphine or methadone» (p. 7) [25].

Narcotic drugs for SMT, which are centrally purchased for state budget funds, are distributed by the Ministry of Health of Ukraine between administrative areas on the basis of the annual applications of heads of structural units for health issues, except for drugs purchased from other sources (patient funds, local budget, funds charitable organizations, philanthropists, etc.) (item 2). Heads of the relevant structural units of the health authorities ensure control over the targeted use of drugs, approve their

distribution and, if necessary, redistribute between subordinate health care institutions (clause 3) [25]. Consequently, monitoring of the implementation and use of methadone and buprenorphine for SMT programs in Ukraine is primarily carried out by the Ministry of Health of Ukraine and its relevant structures as the main agents in organizing and implementing treatment and assisting drug addict patients. In the offices of SMT, the organization of monitoring of methadone or buprenorphine is assigned to the attending physician (clause 12) [25].

Thus, control over the implementation of methadone and buprenorphine for SMT programs in Ukraine is provided at the level of the order of the Ministry of Health of Ukraine. The fact that all states that have signed the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 realize to some extent control over the production, distribution and use ebleniem methadone to reduce the risk associated with its use [6]. According our point of view, control over these drugs in Ukraine should be envisaged at the level of the Law "On Narcotic Drugs, Psychotropic Substances and Precursors".

Control over the use of state budget funds transferred by the Ministry of Health of Ukraine to international specialized organizations is exercised through internal and external audit provided for in the financial regulations, rules and procedures of these organizations. All disputes and disagreements that will not be settled by the sides will be considered in the arbitration court in Geneva (Switzerland) [5, p. 21]. Internal audit is executed by the Accounting Chamber of Ukraine. Thus, it is necessary to distinguish two groups of subjects in the procurement of narcotic drugs with the involvement of international specialized organizations: (1) institutions that carry out state regulation and control in the procurement of narcotic drugs; (2) subjects of procurement of narcotic drugs (customers of procurement procedures and participants in such purchases) - Ministry of Health of Ukraine, international specialized organizations, manufacturers or distributors of narcotic drugs who sell to international specialized organizations.

Conclusions. The analysis of the national legislation regulating the purchase of narcotic drugs from international specialized organizations makes it possible to state that the procedures for their implementation face a number of problems that require immediate resolution. Among them, the most relevant are: (1) underfunding at the expense of the State Budget of Ukraine for the provision of SMT programs; (2) creation of «special» legal conditions for the procurement of SMT drugs with the involvement of international specialized organizations (absence of the price of the drug in the selection criteria of international organizations - prepayment for preparations of 1 or 1.5 years, non-observance of economic competition in this sphere); (3) there is no national legislative control of the use of methadone and buprenorphine for SMT programs; (4) the terms «narcotic drugs» and «psychotropic substances» and «medicines containing narcotic drugs, psychotropic substances and precursors» are not regulated at the level of the Law.

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### **SUMMARY**

### LEGAL REGULATION OF PROCUREMENT OF NAR-COTIC DRUGS IN UKRAINE WITH INVOLVEMENT OF INTERNATIONAL SPECIALIZED ORGANIZATIONS

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The purpose of the study is to analyze specific problems of legal regulation of the procurement of narcotic drugs in Ukraine with the involvement of international specialized organizations. To achieve this goal, statistics have been analyzed concerning the number of people who receive narcotic drugs for the SMT program, the number of their treatment applications, the quantity of drugs purchased for them from the state budget. It is proposed to divide the regulatory legal acts regulating the purchase of narcotic drugs, general and special, and analyze them.

The understanding of legal constructions "state procurement" and "public procurement" in scientific literature, national legislation and international legal documents is analyzed. Two groups of subjects of legal relations in the field of procurement of narcotic drugs with the involvement of international specialized organizations have been distinguished out.

In the course of the study, a number of problems have been identified that require urgent solutions: insufficient budget financing of drug provision for SMT programs; absence of control over the use of methadone and buprenorphine for SMT programs at the legislative level, as well as the differentiation of the terms "narcotic drugs", "psychotropic substances" and "drugs containing narcotic drugs, psychotropic substances and precursors"; absence of the price of the drug in the selection criteria of international organizations, the lack of economic competition in this field, existence of prepayment for SMT drugs for more than one year, which affects the efficiency of using budgetary funds. It is proposed to make a number of changes to the relevant legal acts.

**Keywords:** procurement of narcotic drugs, international specialized organizations, a program of substitution maintenance therapy, the right to health care, medical care.

### РЕЗЮМЕ

ПРАВОВОЕ РЕГУЛИРОВАНИЯ ЗАКУПОК НАРКОТИ-ЧЕСКИХ ЛЕКАРСТВЕННЫХ СРЕДСТВ В УКРАИНЕ С ПРИВЛЕЧЕНИЕМ МЕЖДУНАРОДНЫХ СПЕЦИАЛИ-ЗИРОВАННЫХ ОРГАНИЗАЦИЙ

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Целью исследования послужил анализ отдельных проблем правового регулирования закупок наркотических лекарственных средств в Украине с привлечением международных

специализированных организаций. Для достижения указанной цели были тщательно изучены статистические данные, отображающие количество лиц, получающих наркотические лекарственные средства для програм ЗПТ, число их обращений за лечением, количество препаратов, закупленных для них за средства государственного бюджета. Нами предложено разделить нормативно-правовые акты, регулирующие закупки наркотических лекарственных средств, на общие и специальные, проведен их детальный анализ.

Изучено понимание правовых конструкций «государственная закупка» и «публичная закупка» в научной литературе, национальном законодательстве и международно-правовых документах. Выделены две группы субъектов правоотношений в сфере закупок наркотических лекарственных средств с привлечением международных специализированных организаций. В процессе исследования установлен ряд проблем, требующих неотложного решения: недостаточное бюджетное финансирование обеспечения препаратами для программ ЗПТ, отсутствие на законодательном уровне контроля использования метадона и бупренорфина для программ ЗПТ, необходимость разграничения терминов «наркотические средства», «психотропные вещества» и «лекарственные средства, содержащие наркотические средства, психотропные вещества и прекурсоры», отсуствие в критериях выбора международных организаций цены препарата, не соблюдение экономической конкуренции в этой сфере, наличие предоплаты за препараты ЗПТ втечение одного года и более, что влияет на эффективность использования бюджетных средств. Предложено внести ряд изменений в соответствующие нормативно-правовые акты.

რეზიუმე

უკრაინაში ნარკოტიკული საშუალებების საერთაშორისო სპეციალიზებული ორგანიზაციების ჩართულობით შესყიდვის სამართლებრივი რეგულაცია

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კვლევის მიზანს წარმოადგენდა უკრაინაში ნარ-კოტიკული საშუალებების საერთაშორისო სპეციალიზებული ორგანიზაციების ჩართულობით შესყიდვის სამართლებრივი რეგულაციის პრობლემების ანალიზი. ამ მიზნით დეტალურადაა შესწავლილი სტატისტიკური მონაცემები, რომელიც ასახავს ადამიანების რაოდენობას, ვინც იღებდა ნარკოტიკულ სამკურნალწამლო საშუალებებს, ასევე, მათი მიერ მკურნალობისათვის მიმართვიანობის ოდენობას, სახელმწიფო ბიუჯეტის ხარჯზე მათთვის შეძენილი პრეპარატების რაოდენობას. ავტორების მიერ მოწოდებულია ნარკოტიკული სამკურნალწამლო საშუალებების შესყიდეების მარეგულირებელი ნორმატიულ-სამართლებრივი აქტების დაყოფა ზოგად და სპეციალურ აქტებად,ჩატარებული მათი დეტალური ანალიზი.

შესწავლილია "სახელმწიფო შესყიდვის" და "საჯარო შესყიდვის" ცნებების სამართლებრივი კონსტრუქციები სამეცნიერო ლიტერატურაში, ეროგნულ კანონმდებლობასა და საერთაშორისო სამართლებრივ

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ჯგუფი. კვლევის პროცესში დადგენილია გადაუდე-

ბელი გადაწყვეტის საჭიროების პრობლემები: საბიუ-

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