

## Research Article



## Organizational and Legal Analysis of the Pharmaceutical Provision for the Most Common Diseases of Society

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### ABSTRACT

The statistical data shows that cardiovascular diseases, type II diabetes mellitus and bronchial asthma are among the most common non-communicable diseases both in the territory of the Kharkiv region and Ukraine as a whole. Therefore, it was of interest to conduct an organizational and legal analysis of the pharmaceutical provision of the most common diseases, which occupy leading positions in the statistical data in Ukraine and in the world, on example of medicines, the cost of which is subject to reimbursement. During the study conducted an organizational and legal analysis of pharmaceutical provision of the most widespread diseases in Ukraine and in the world on example of medicines, the cost of which is subject to compensation. Studied the current regulatory framework on the reimbursement of the cost of medicines included in the state program "Available medicines". Analyzed the registry of these medicines, which includes 23 international non-proprietary names, by the number of trade names, the number of medicines that released free of charge and with surcharges, manufacturers and the validity period of the registration certificates. Established that under the program "Available medicines" the state fully (100%) compensates for the cost of 47 medicines, partially (with surcharge) the state compensates for the cost of 192 medicines (the patient pays an average of 10-30% of the cost).

**Keywords:** medicines, available medications, reimbursement, cardiovascular diseases, diabetes mellitus, bronchial asthma.

### INTRODUCTION

The main Law of Ukraine, namely the Constitution of Ukraine in Article 3 proclaimed that human, its life and health, honor and dignity, inviolability and security recognized in Ukraine as the highest social value. In context of practical implementation of the policy in the field of medicines circulation in Ukraine, the following principles are respected: – population's health is a priority, therefore citizens provided with the necessary set of preventive and curative measures; – population's access to essential medicines is obligatory; – correction of the activity of law enforcement agencies in the fight against organized crime, falsification of medicines, etc.<sup>1</sup>.

Recent statistics indicates that Ukraine has a significant incidence of cardiovascular disease: since 1991, there has been a steady tendency towards an increase in the incidence of diseases of the circulatory system – in this period it has doubled (to 4972 cases per 100 thousands of population in 2013), and their prevalence in three times (up to 58429 cases per 100 thousands). In the structure of the morbidity of an adult population, hypertension is prevalent among the cardiovascular diseases – 41%, ischemic heart disease – 28%, cerebrovascular diseases – 16%. According to WHO forecasts, by 2030, more than 23 million people will die from the cardiovascular diseases and they will hold the lead among the causes of death of the planet's population<sup>2</sup>.

In addition, according to WHO, about 3% of the world's population suffers from diabetes mellitus and 10-20% of the total number of these patients are children. Only in the period from 1990 to 2010, the total number of patients with diabetes increased almost threefold and with restrained predictions of experts in 2030 will reach 552 million people<sup>3</sup>.

Among the diseases that children and young people suffer more often, bronchial asthma should be distinguished: in 2010, 210 thousand patients with asthma registered in Ukraine<sup>4</sup>.

Mentioned diseases are the most common non-infectious diseases in the territory of the Kharkiv region. To reduce mortality from these diseases, the state has developed a number of legislative, regulatory and guidance documents, which allocate medicines whose cost is subject to reimbursement<sup>1</sup>. Our goal was to conduct an organizational and legal analysis of pharmaceutical provision for the most common diseases, which occupy leading positions in the statistical data in Ukraine and in the world, on the example of medicines, the cost of which is subject to reimbursement.

### MATERIALS AND METHODS

Used normative and legal documents; statistical data of WHO, the Ministry of Healthcare of Ukraine, the Healthcare Administration of Kharkiv Regional State Administration. To achieve this goal, used documentary,



regulatory, marketing, mathematical and tabular methods of analysis<sup>5-13</sup>.

Marketing researches of medicines, the cost of which is subject to reimbursement, from the program "Available medicines" carried out in the directions: quantitative analysis of trade names of medicines; quantitative analysis of medicines, released free of charge and with surcharge; analysis by manufacturers; analysis of terms of registration certificates.

The method of analysis of the terms of registration of medicines conducted on the basis of the "Procedure for state registration (re-registration) of medicines", approved by the Resolution of the Cabinet of Ministers of Ukraine dated May 26, 2005 No. 376, which stipulates that "an authorized medical certificate should be issued to an applicant, and it indicates the validity period during which the medicine is permitted for use in Ukraine", as well as the order of the Ministry of Healthcare of Ukraine dated 27.07.2016 No. 773. The specified order approved an updated form of the registration certificate for medicines, including medical immunobiological preparations, in particular, it provides for the indication of the period during which the use of registered or re-registered medicine is approved, namely: for 5 years – in case of registration and individual cases of re-registration of medicines; indefinitely – in case of re-registration of medicines, except when the Ministry of Healthcare of Ukraine decides to carry out additional re-registration for 5 years for well-founded reasons related to pharmacovigilance; until March 31, 2019 – in case of registration of a medicine that is to be procured with the participation of international specialized organizations in order to provide state target programs<sup>7,11</sup>.

## RESULTS AND DISCUSSION

Statistical data due to the lack of physical and economic availability of basic medicines and medical services. At the same time, a significant problem is that patients without consulting a doctor buy drugs that do not meet the diagnosis and do not coincide with the rates of prevalence of the disease.

According to the results of the research of the pharmaceutical market of Ukraine, conducted by the Antimonopoly Committee of Ukraine, since 2014, the cost of medicines in pharmacy facilities has increased rapidly. Such objective factors as the exchange rate of the national currency, the level of inflation, changes in the taxation system, the introduction of additional import duties, etc. had a significant impact on the formation of the value of the drug.

In order to avoid unreasonable overestimation of medicines prices in most developed countries, there is a practice of state regulation of prices for medicines.

In pursuance of the Resolution of the Cabinet of Ministers of Ukraine dated November 9, 2016, No. 862, as of 01.04.2017, the Kharkiv region and the city of Kharkiv

introduced state regulation of prices for medicines procured, which procured and whose value reimbursed for budgetary funds, by setting by the Ministry of Healthcare of Ukraine marginal wholesale prices. The action of this resolution applies to the registered in Ukraine medicines for pharmaceutical provision for above-mentioned diseases<sup>8</sup>.

It should be noted that according to Annex 7 of the Law of Ukraine "On the State Budget of Ukraine for 2017"<sup>5</sup> in the Kharkiv region there is a targeted subvention amounting to 34875,8 thousand UAH (Kharkiv city – 15805820 UAH, district districts – 19069980 UAH) for the reimbursement of the cost of medicines for pharmaceutical provision and for the implementation of the project.

Taking into account, that at the time of the approval of the regional budget of the Kharkiv region for 2017, as well as amendments thereto, the procedure for use of subvention funds for the reimbursement of the cost of medicines for the treatment of certain diseases was not approved at the level of the Cabinet of Ministers of Ukraine, the indicated volumes of target expenditures were left at the level the regional budget and not distributed.

Organizational and legal measures of the healthcare department of Kharkiv Regional State Administration for communal healthcare institutions at the regional level on example of Kharkiv region shown on Fig. 1.

Resolution of the Cabinet of Ministers of Ukraine dated March 17, 2017 No. 152<sup>10</sup> defines the Procedure for the reimbursement of the cost of medicines and the Procedure for determining the amount of reimbursement of the cost of medicines, the cost of which is subject to reimbursement.

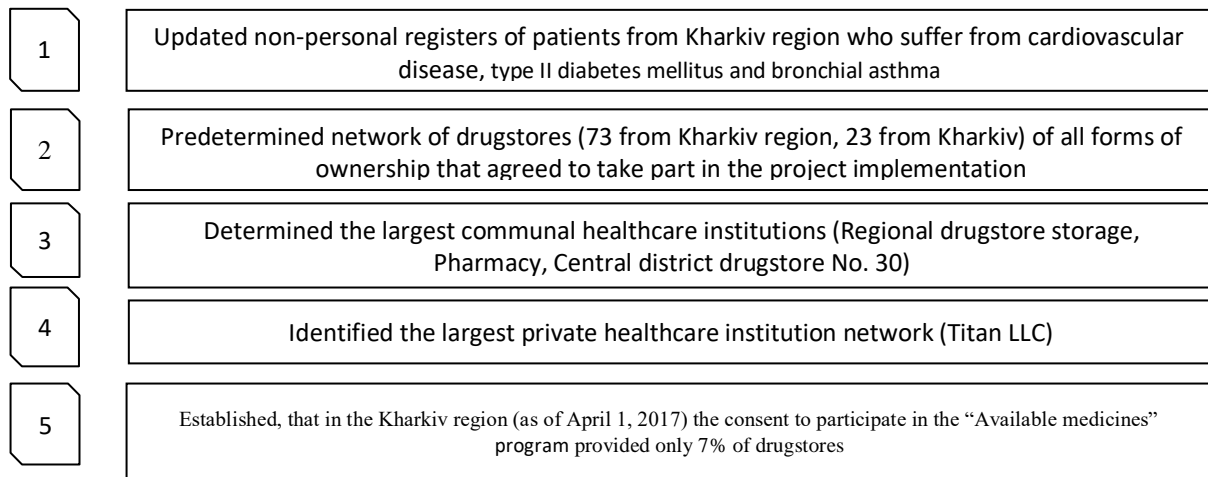
At the same time, the Resolution of the Cabinet of Ministers of Ukraine dated March 10, 2017 No. 181 approved the Procedure and Conditions for granting a subsidy from the state budget to local budgets for the reimbursement of the cost of medicines for the treatment of certain diseases<sup>9</sup>.

Mentioned procedure, in particular, stipulates that the distribution of the subvention provided in the regional budgets is carried out between the local budgets of the administrative and territorial units of the region based on statistical data on the number of persons suffering from cardiovascular diseases, type II diabetes and bronchial asthma, that subvention managers in local budgets and determined by decisions on such budgets in accordance to legislation.

Thus, today, prior to the adoption of the sessional decision of the Kharkiv Regional Council, and in the future – the sessional decisions of local self-government bodies of specific administrative-territorial units of the region, it is not possible to provide information on the administrators of the targeted subvention, as well as the

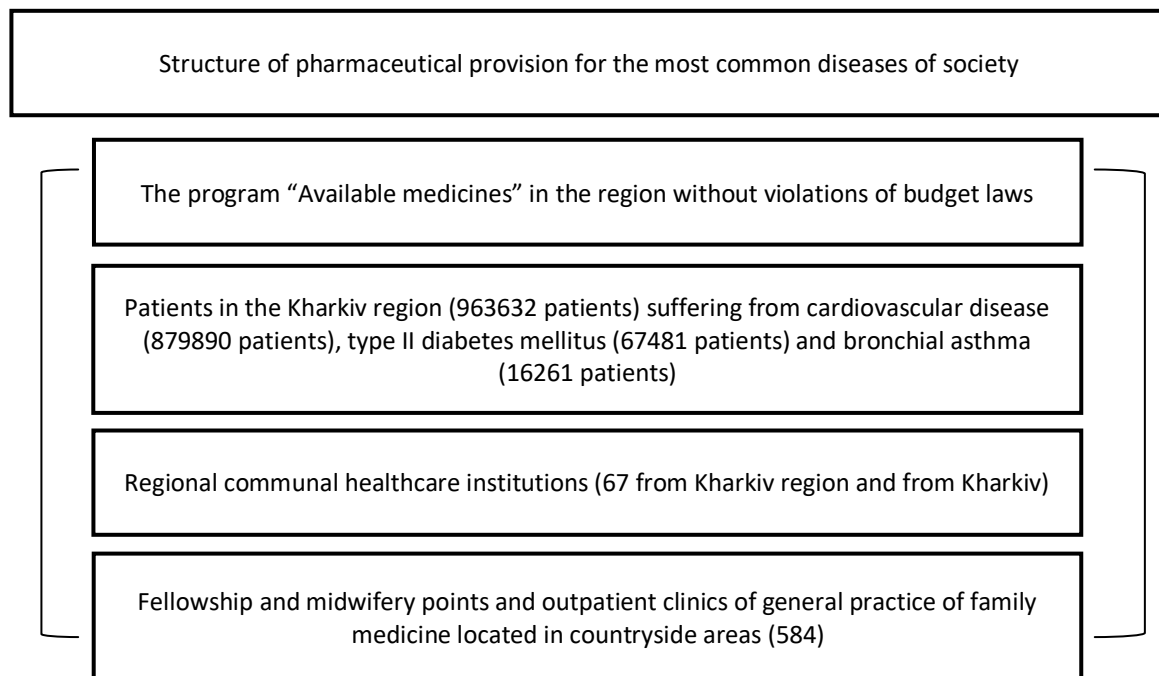


list of pharmacy establishments that have entered into agreements with these for spending funds.



**Figure 1:** Organizational and legal measures of healthcare department of Kharkiv Regional State Administration for communal healthcare institutions

The structure of the pharmaceutical provision with medicines of the most common diseases of the society, the cost of which is recoverable in the Kharkiv region, shown on Fig. 2



**Figure 2:** Structure of pharmaceutical provision for the most common diseases of society with medicines, which are subject to reimbursement in Kharkiv region

In January 2018, the Ministry of Healthcare of Ukraine by an order dated January 22, 2018 No. 111 approved a new register of medicines for the treatment of above-mentioned diseases, the cost of which is subject to reimbursement. For pharmaceutical provision, the maximum reference price of a medicines' manufacturer for 23 international non-proprietary names (INN) has been set. The register of medicines, the cost of which is subject to reimbursement, according to the government program "Available medicines" includes 23 INNs of

medicines, which corresponds to 239 trade names (TN) of medicines<sup>6</sup>.

The detailed analysis of the INNs that included to the program "Available medicines", the number of TNs, the number of medicines, which are released free of charge and with an additional payment, by manufacturers and the term of action of the registration certificate as of February 2018 given in the Tables 1-6.

**Table 1:** Characteristics of medicines for the treatment of cardiovascular disease by the quantitative index of TNs and type of reimbursement

No.	INN	TN	Quantity of medicines by the type of reimbursement	
			100%	Additional payment
1.	Amiodarone	8	1	7
2.	Amlodipine	36	2	34
3.	Atenolol	4	1	3
4.	Bisoprolol	29	6	23
5.	Verapamil	4	1	3
6.	Hydrochlorothiazide	1	1	-
7.	Digoxin	2	2	-
8.	Enalapril	18	3	15
9.	Isosorbidedinitrate	1	1	-
10.	Carvedilol	13	4	9
11.	Clopidogrel	23	3	20
12.	Losartan	11	1	10
13.	Metoprolol	8	1	7
14.	Glyceryltrinitrate	3	1	2
15.	Simvastatin	14	4	10
16.	Spirolactone	5	2	3
17.	Furosemide	4	2	2
	Total:	184	36	148

**Table 2:** Characteristics of medicines for the treatment of cardiovascular disease by manufacturers and the term of registration certificate

No.	INN	Quantity		Unlimited term of registration certificate
		Domestic	Foreign	
1.	Amiodarone	5	3	2
2.	Amlodipine	8	28	11
3.	Atenolol	4	-	3
4.	Bisoprolol	15	14	-
5.	Verapamil	4	-	2
6.	Hydrochlorothiazide	1	-	1
7.	Digoxin	2	-	1
8.	Enalapril	14	4	4
9.	Isosorbidedinitrate	1	-	1
10.	Carvedilol	7	6	-
11.	Clopidogrel	11	12	3
12.	Losartan	4	7	-
13.	Metoprolol	4	4	4
14.	Glyceryltrinitrate	3	-	1
15.	Simvastatin	2	12	3
16.	Spirolactone	2	3	1
17.	Furosemide	4	-	1
	Total:	91	93	38

The data from Tables 1 and 2 testify that to the register of medicines from the program "Available medicines" included 17 INNs of medicines for the pharmaceutical provision of cardiovascular disease, which are presented by 184 TNs, of both domestic (91) and foreign (93) production. INNs Amlodipine (36), Bisoprolol (29) and Clopidogrel (23), and a minority of TN (1) – INN Hydrochlorothiazide and Isosorbidedinitrate, represent

most of the TNs. Among the medicines for the treatment of cardiovascular system, 100% of the reimbursement by the state is subject to 36, and other 148 medicines can be purchased with an additional payment; 38 TNs of medicines have an unlimited term of action of registration certificate, except for INNs Bisoprolol, Carvedilol, Losartan.

**Table 3:** Characteristics of medicines for the treatment of type II diabetes mellitus by the quantitative index of TNs and type of reimbursement

No.	INN	TN	Quantity of medicines by the type of reimbursement	
			100%	Additional payment
1.	Glibenclamide	3	3	-
2.	Gliclazide	8	1	7
3.	Metformin	32	3	29
	Total:	43	7	36

**Table 4:** Characteristics of medicines for the treatment of type II diabetes mellitus by manufacturers and the term of registration certificate

No.	INN	Quantity		Unlimited term of registration certificate
		Domestic	Foreign	
1.	Glibenclamide	3	-	1
2.	Gliclazide	5	3	3
3.	Metformin	26	6	10
	Total:	34	9	14

Table 3 and 4 gives information that there are 43 TNs of medicines for the treatment of type II diabetes, corresponding to three INNs, mainly domestic production (34). The majority of TNs represented by INN Metformin (32). Among the listed medicines, seven medicines are subject to 100% reimbursement, and 14 medicines have an unlimited expiration date of registration certificates.

**Table 5:** Characteristics of medicines for the treatment of bronchial asthma by the quantitative index of TNs and type of reimbursement

No.	INN	TNs	Quantity of medicines by the type of reimbursement	
			100%	Additional payment
1.	Beclometasone	3	1	2
2.	Budesonide	6	2	4
3.	Salbutamol	3	1	2
	Total:	12	4	8

**Table 6:** Characteristics of medicines for the treatment of bronchial asthma by manufacturers and the term of registration certificate

No.	INN	Quantity		Unlimited term of registration certificate
		Domestic	Foreign	
1.	Beclometasone	-	3	2
2.	Budesonide	-	6	2
3.	Salbutamol	1	2	-
	Total:	1	11	4

For the treatment of bronchial asthma (Table 5 and 6), 3 INNs included to the register, which are represented by 12 TNs, of which 4 are subject to 100% reimbursement by

the state. The majority of TNs represented by INN Budesonide – 6. The vast majority of medicines are of



foreign production – 11. Unlimited validity of registration certificate have four medicines, except Salbutamol.

Thus, according to the program "Available medicines" (Tables 1-6), the state completely (100%) compensates for the cost of 47 medicines, in particular for treatment:

- i. Cardiovascular disease – 36 medicines (for example, amiodarone /production Ukraine/);
- ii. Type II diabetes mellitus – 7 medicines (for example, Gliclazide /production Ukraine/);
- iii. Bronchial asthma – 4 medicines (for example, Salbutamol Neo /production Ukraine/).
- iv. The percentage of medicines, the cost of which completely compensated by the state, is 19.66%.
- v. Partly (with surcharge) the state compensates for the cost of 192 medicines (patient pays an average of 10-30% of the cost), in particular for treatment:
- vi. Cardiovascular disease – 148 drugs (for example, amiodarone /production Ukraine/ retail price – 53.33 UAH, the amount of additional payment to the patient is 10.02 UAH);
- vii. Type II diabetes mellitus – 36 medicines (for example, Gliclazide /production Ukraine/ retail price – 48.90 UAH, the amount of additional payment by the patient is 4.91 UAH);
- viii. Bronchial asthma – 8 medicines (for example, Salbutamol /production France/ retail price – 82.84 UAH, the amount of additional payment by the patient is 17.87 UAH).

Among medicines in the "Available drugs" program, domestic pharmaceutical manufacturers produce 52.7%, while 47.3% are foreign.

A total of 23.43% of the medicines have registration certificate for an unlimited period. Registration certificate of other medicines ends in different periods from 2018 to 2022.

In order to resolve issues that arise from doctors when prescribing prescriptions to F-1 forms for patients and prescribing the remnants of old prescription forms, the Ministry of Healthcare of Ukraine proposed to act as follows:

- i. The doctor is allowed to use the forms of the old sample before July 1, 2017, with the corresponding stamp of red color "Cost to be refunded" when prescribing the medicine, the cost of which is subject to reimbursement;
- ii. The pharmacy specialist at the time of the delivery of the medicine, the cost of which is subject to refund, on the recipe of the old sample, it is necessary to put a stamp of red color "released for free" or "released with an additional payment" while the recipe remains in the pharmacy for further reporting.

## CONCLUSION

Based on the study of the current regulatory framework, analyzed the register of medicines, the cost of which is subject to reimbursement under the government program "Available medicines". Determined that the register includes 23 INNs, which correspond to 239 TNs, including 184 for the treatment of cardiovascular disease, 43 for type II diabetes and 12 for bronchial asthma.

Established that under the program "Available medicines" the state fully (100%) compensates for the cost of 47 medicines, in particular for treatment: cardiovascular disease – 36 medicines (for example, Amiodarone /production Ukraine/); type II diabetes – seven medicines (for example, Gliclazide /production Ukraine/); bronchial asthma – four medicines (for example, Salbutamol Neo /production Ukraine/). The percentage of medicines, the cost of which completely compensated by the state, is 19.66%.

Partly (with surcharge) the state compensates for the cost of 192 medicines (the patient pays an average of 10-30% of the cost), in particular for treatment of: cardiovascular disease – 148 medicines (for example, amiodarone /production Ukraine/ retail price – 53.33 UAH, the amount of additional payment by patient is 10.02 UAH); Type II diabetes mellitus – 36 medicines (for example, Gliclazid /production Ukraine/ retail price – 48.90 UAH, the amount of additional payment by patient is 4.91 UAH); bronchial asthma – 8 medicines (for example, Salbutamol /production France/ retail price – 82.84 UAH, the amount of additional payment by patient is 17.87 UAH).

Among medicines that are included in the "Available medicines" program, 52.7% produced by domestic pharmaceutical manufacturers, and 47.3% are foreign. A total of 23.43% of the medicines have registration certificate for an unlimited period of time. The registration certificates of other medicines ends in different periods from 2018 to 2022.

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