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FORENSIC PHARMACY: ANALYSIS OF COMPLAINTS ABOUT THE PHARMACEUTICAL PROVISION FOR PRIVILEGED CATEGORIES OF PATIENTS IN UKRAINE (EXPERIMENTAL RESEARCH)

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ABSTRACT

The article presents the results of the research from position of forensic pharmacy concerning analysis of complaints about the pharmaceutical provision for privileged categories of patients in Ukraine. Analyzed world experience of the reimbursement system (reference pricing) in pharmaceutical provision for privileged categories of citizens comparing to existing system in Ukraine. Studied complaints of privileged contingents of patients concerning pharmaceutical supply in various health care facilities. Based on results created a matrix of complaints of privileged contingents of patients regarding unsatisfactory pharmaceutical provision. Based on the matrix of complaints, three regional lists of drugs were developed with the further development of organizational and legal measures to increase the level of pharmaceutical provision of privileged contingents of patients.

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Introduction. Benefits in Ukraine are provided on a categorical basis, according to the citizen's belonging to a certain privileged category depending on the social status or professional activity defined by law. Privileges are established for various purposes, as a reward to the state, to ensure an increased level of their social guarantees or as social support to ensure an adequate standard of living [1, 2].

In Ukraine, the main method of the state pharmaceutical privileged categories of patients remains public procurement for budget funds. In addition, at various times, a system of "preferential prescriptions", pilot projects to reimburse the cost of drugs, health insurance funds were introduced into practice. The ideas of insurance medicine have been actively discussed for a long time, but without any real steps for its implementation [3, 4].

Disadvantages of the state system of pharmaceutical provision of privileged contingents of patients in Ukraine include overstated costs for the purchase of drugs due to corruption schemes, lack

of market pricing, a huge number of formal requirements for tender documents, lack of long-term procurement planning by the state for manufacturing companies [5, 6].

That is why the search for alternative methods of pharmaceutical provision for privileged categories of patients at the expense of the state remains relevant.

The world experience of the reimbursement system (reference pricing) is the most cost-effective and optimal, as it implements the principle of targeted subsidies. Reference pricing in the world is primarily aimed at establishing the level of reimbursement at the expense of the state, and retail prices are influenced by market mechanisms and the laws of free competition. This mechanism is used by the vast majority of countries and in practice has reduced health care costs by up to 50% [7, 8, 9].

For the first time in Ukraine, preferential pharmaceutical provision with elements of reimbursement of certain categories of patients with certain diseases was launched in 1998. Unfortunately, this area is developing less actively. Sufficient funds are not allocated for the pharmaceutical provision of beneficiaries with medicines. On the example of preferential pharmaceutical supply of medicines to people affected by the Chernobyl disaster, we can see how the financial support of the state went to a separate fund, which is replenished by direct mandatory payments from the population [10, 11].

In 2012, Ukraine launched the first pilot project to reimburse the cost of drugs for the treatment of people with hypertension. Despite some positive results at the initial stage of the project, such as lower antihypertensive drugs and positive indicators of real reimbursement to patients, today most pharmaceutical companies treat it with irritation rather than interest in participating.

The main feature of the pharmaceutical supply of different contingents of patients is the social orientation. Therefore, it is necessary to actively develop the social potential of health care facilities (hospitals, clinics, pharmacies). The activities of the health care facilities include the implementation of costs, which are the basis for the formation of pricing policy for drugs. In market conditions, the main condition for effective pharmaceutical provision of privileged categories of patients is transparency, completeness, reliability, honesty and efficiency of information about the costs that form the cost of drugs [12, 13, 14].

Purpose of the research was to analyze the complaints of privileged contingents of patients for pharmaceutical supply in health care facilities (hospitals, clinics, pharmacies) from the position of forensic pharmacy and pharmaceutical law.

Materials and Methods. The current research was carried out using the system approach during 2017–2020. The materials were questionnaires of employees of health departments among a number of regional state administrations, 58 health care institutions, 18 communal and private pharmacies that provide pharmaceutical benefits to privileged categories of patients.

The information base of the study consisted of scientific works of foreign and domestic scientists on issues related to the organization of pharmaceutical business, management, forensic pharmacy, pharmaceutical supply, pricing policy for drugs [15, 16, 17].

Modern research methods were used: normative and legal, documentary, retrospective, bibliographic, systemic, forensic-pharmaceutical, sociological (questionnaire survey), comparative, marketing, graphic, mathematical analysis. Mathematical processing and statistical evaluation of data was performed using Microsoft Excel.

The study of the article is a fragment of research work of the Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, deadline 2016-2020) and "Pharmaceutical and medical law: integrated approaches to the drug circulation system from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number D/21U000031, deadline 2021-2026).

Research results. Five thousand fifty complaints from privileged categories of patients about unsatisfactory pharmaceutical supply were processed according to a specially developed questionnaire [18].

Found that 61% of complaints of privileged patients (women accounted for 38%; men – 62%) were related to late or incomplete provision of prescription drugs. Violation of the rights of privileged categories of patients to receive drugs on discounted and free prescriptions of doctors was recorded in 58% of complaints.

At the preparatory stage of the study, a superficial analysis of the study materials was performed in order to eliminate improperly completed questionnaires and calculate the minimum number of them to obtain representative data of the study results according to the formula:

$$n = \frac{N}{1 + 0.015 \cdot N}$$

where n – is the number of questionnaires;
 N – is the total number of respondents.

In the course of the study, a matrix of complaints based on patient reports of unsatisfactory pharmaceutical supply of drugs of different clinical and pharmacological, classification and legal and nomenclature and legal groups was constructed (Fig. 1).

Based on the matrix of complaints, appropriate lists of drugs were developed with the further development of organizational and legal measures to increase the level of pharmaceutical provision of privileged contingents of patients.

Revealed that the reference pricing mechanism in the world is primarily aimed at establishing the level of reimbursement at the expense of the state, and retail prices are influenced by market mechanisms and the laws of free competition. This mechanism is used by the vast majority of EU countries and in practice has reduced health care costs by up to 50% depending on the state [19, 20, 21].

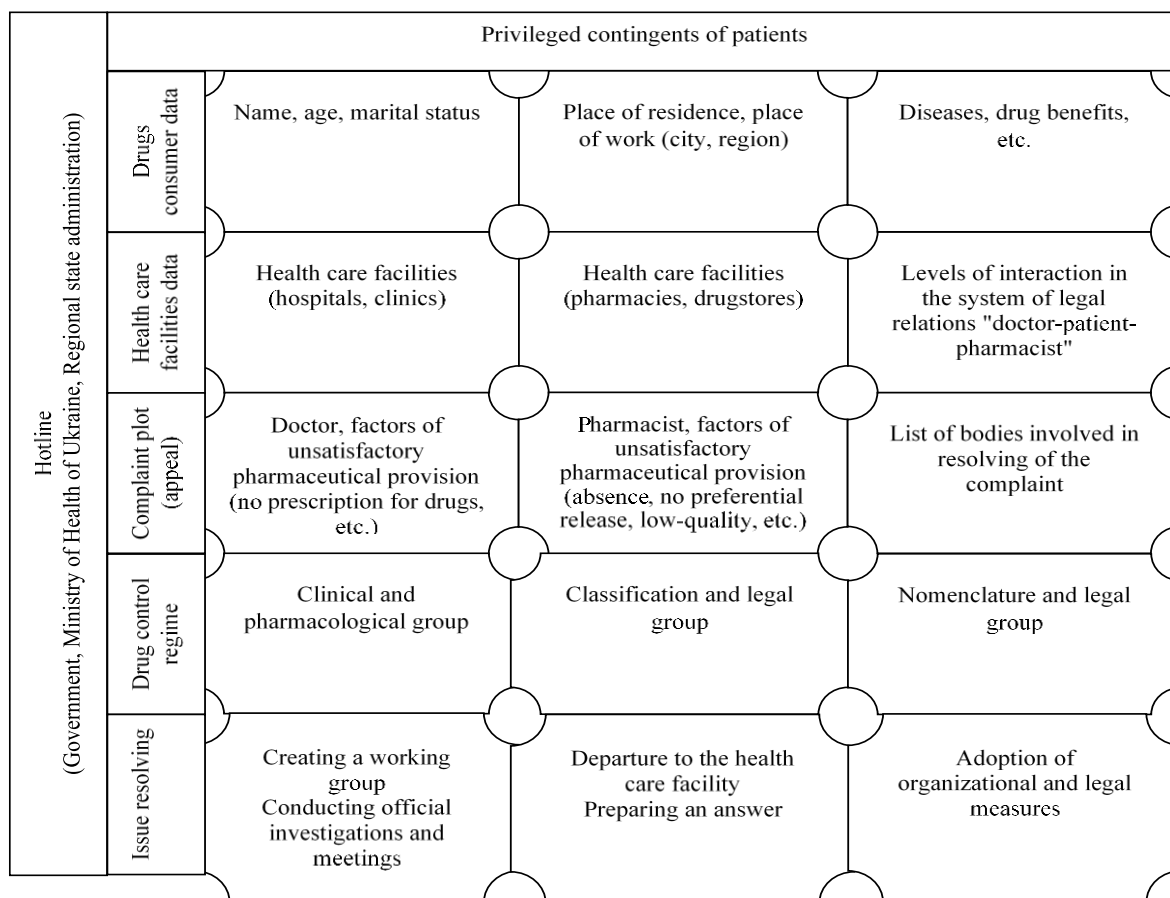


Fig. 1. Matrix of complaints of privileged contingents of patients regarding unsatisfactory pharmaceutical provision (source: own development)

Discussion. In accordance to the ATC classification, the clinical and pharmacological distribution of drugs by five clinical and pharmacological groups, which appeared in the complaints of privileged contingents of patients [22]:

- A - Drugs affecting the digestive system and metabolism (9.5%)
- C - Drugs affecting the cardiovascular system (44.5%)
- D - Dermatological products (3.2%)
- M - Medications for musculoskeletal system (1.6%)
- N - Drugs acting on the nervous system (41.2%)

Thus, the unsatisfactory level of pharmaceutical provision of privileged categories of patients among the drugs of clinical and pharmacological group C "Drugs that affect the cardiovascular

system" (44.5% of complaints); the share of complaints about drugs of group N acting on the nervous system is 41.2%; group A - 9.5%.

Based on the study, three regional lists of drugs for pharmaceutical support of privileged categories of patients were compiled.

List 1 included OTC drugs of the general group on complaints of privileged contingents of patients (Table 1). The biggest number of OTC drugs of the general group belongs to the ATC codes A and N (by 40% respectively).

Table 1. Regional list one. OTC drugs of the general group on complaints of privileged contingents of patients (source: own development)

No.	INN	ATC code	Clinical and pharmacological group
1	Fish oil oxidation products	D08AX	Antiseptics and disinfectants
2	Silymarin	A05BA03	Hepatoprotective drugs
3	Hyperici herba, Passiflorae herba, Valerianae radix, Crataegi folium cum flore, Lupuli flos, Melissa herba, Sambusi flos, Guaifenesin	N05CM	Sedatives
4	Sea buckthorn oil	A02X	Drugs that affect the digestive system and metabolism. Drugs for the treatment of acid-dependent diseases
5	Metamizole sodium, combinations with psycholeptics	N02BB72	Analgesics antipyretics

List two included prescription drugs of the general group on the complaints of privileged contingents of patients (Table 2).

Table 2. Regional list two. Prescription drugs of the general group on complaints of privileged contingents of patients (source: own development)

No.	INN	ATC code	Clinical and pharmacological group
1	Deproteinized hemoderivative from calf blood	A16AX	Drugs that affect the digestive system and metabolic processes
2	Chlorpromazine	N05AA01	Antipsychotic drugs. Phenothiazine derivatives with aliphatic structure
3	Amlodipine	C08CA01	Selective calcium antagonists with a predominant effect on blood vessels. Dihydropyridine derivatives
4	Atenolol	C07AB03	Selective β -adrenoceptor blockers
5	Metoprolol	C07AB02	Selective β -adrenoceptor blockers
6	Barbiturates in combination with other drugs	N05CB02	Hypnotics and sedatives. Barbiturates in combination with drugs of other groups
7	Essential phospholipids	A05BA	Hepatotropic drugs
8	Amiodarone	C01BD01	Antiarrhythmic drugs, class III
9	Levodopa and decarboxylase inhibitor	N04BA02	Antiparkinsonian drugs. Dopaminergic drugs. DOPA and derivatives. Levodopa with decarboxylase inhibitor
10	Nalbuphine	N02AF02	Analgesics. Opioids. Morphine derivatives
11	Nimesulide	M01AX17	Non-selective nonsteroidal anti-inflammatory drugs
12	Metamizole sodium, Fenpiverinium bromide, Pitofenone hydrochloride	A03DA02	Synthetic anticholinergics in combination with analgesics
13	Ethanol	D08AX08	Antiseptics and disinfectants

Important to note, that among the prescription drugs of the general group on the complaints of privileged contingents of patients (Table 2) the first three positions on the unsatisfactory level of pharmaceutical supply were drugs with three ATC codes: "N" drugs acting on the nervous system (Aminazine, Valocordine, Levome, etc.) - 30.8%; "C" drugs that affect the cardiovascular system (Amlodipine, Betaloc, Atenolol etc.) – 30.8%; "A" drugs that affect the digestive system and metabolism (Actovegin, Essentiale forte H, Renalgane) – 23.0%.

As the place of ranking received the most complaints from the privileged contingents of patients regarding the pharmaceutical supply of drugs that affect the cardiovascular system, it was further analyzed, systematized, copied and compiled Regional List three – drugs of the general group affecting the cardiovascular system for complaints of different contingents of patients (Table 3).

Table 3. Regional list three. Drugs of the general group affecting the cardiovascular system on the complaints of privileged contingents of patients (source: own development)

No.	INN	ATC code	Clinical and pharmacological group	Nomenclature and legal group
1	2	3	4	5
1	Amlodipine	C08CA01	Selective calcium antagonists with a predominant effect on blood vessels. Dihydropyridine derivatives	By the F-1 recipe
2	Atenolol	C07AB03	Selective β -adrenoceptor blockers	By the F-1 recipe
3	Adenosine	C01EB10	Cardiac drugs. Adenosine	By the F-1 recipe
4	Enalapril	C09AA02	Angiotensin-converting enzyme inhibitors	By the F-1 recipe
5	Metoprolol	C07AB02	Selective β -adrenoceptor blockers	By the F-1 recipe
6	Bisoprolol	C07AB07	Selective β -adrenoceptor blockers	By the F-1 recipe
7	Lisinopril and amlodipine	C09BB03	Combined drugs of ACE inhibitors	By the F-1 recipe
8	Enalapril	C09AA02	Angiotensin-converting enzyme inhibitors	By the F-1 recipe
9	Enalapril	C09AA02	Angiotensin-converting enzyme inhibitors	By the F-1 recipe
10	Enalapril and diuretics	C09BA02	Combined drugs of ACE inhibitors. Captopril and diuretics	By the F-1 recipe
11	Calcium gluconate	A12AA03	Calcium preparations	OTC
12	Captopril and diuretics	C09BA01	Combined drugs of ACE inhibitors. Captopril and diuretics	By the F-1 recipe
13	Bisoprolol	C07AB07	Selective β -adrenoceptor blockers	By the F-1 recipe
14	Amiodarone	C01BD01	Antiarrhythmic drugs, class III	By the F-1 recipe
15	Lacidipine	C08CA09	Calcium channel blockers. Selective calcium channel blockers with a predominant effect on blood vessels	By the F-1 recipe
16	Lisinopril	C09AA03	Angiotensin-converting enzyme inhibitors	By the F-1 recipe
17	Lisinopril	C09AA03	Angiotensin-converting enzyme inhibitors	By the F-1 recipe
18	Betaxolol	C07AB05	Selective β -adrenoceptor blockers	By the F-1 recipe
19	Losartan	C09CA01	Agents acting on the renin-angiotensin system. Simple drugs of angiotensin II receptor antagonists	By the F-1 recipe
20	Meldronium	C01EB22	Cardiac drugs	By the F-1 recipe
21	Nebivolol	C07AB12	Selective β -adrenoceptor blockers	By the F-1 recipe
22	Trimetazidine	C01EB15	Cardiac drugs	By the F-1 recipe
23	Propafenone	C01BC03	Drugs for the treatment of heart disease. Antiarrhythmic drugs of the IC class	By the F-1 recipe
24	Amlodipine	C08CA01	Selective calcium antagonists with a predominant effect on blood vessels. Dihydropyridine derivatives	By the F-1 recipe

Based on the calculations, it was proved that the most unsatisfactory level of pharmaceutical supply received complaints about drugs Amlodipine, Atenolol, Adenosine, Enalapril, Amiodarone (95.8%).

Conclusions. 1. It is substantiated that the main feature of pharmaceutical provision of privileged contingents of patients is social orientation. It is proved that it is necessary to actively develop the social potential of health care facilities in the format of transparency, completeness, reliability, and efficiency of information about the costs that form the cost of drugs.

2. From the position of forensic pharmacy, five thousand fifty complaints were processed from privileged categories of patients regarding unsatisfactory pharmaceutical supply according to a specially developed questionnaire.

3. In the course of the study, a matrix of complaints based on patient reports of unsatisfactory pharmaceutical supply of drugs of different clinical-pharmacological, classification-legal and nomenclature-legal groups was constructed.

4. On the basis of the matrix of complaints, three regional lists of drugs were developed with the further development of organizational and legal measures to increase the level of pharmaceutical provision of privileged contingents of patients.

5. It is noted that the reference mechanism of drug pricing is aimed at establishing the level of reimbursement at the expense of the state and reducing costs to 50% for pharmaceutical provision of privileged categories of patients.

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