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**THE PRINCIPLES OF THE
PHARMACEUTICAL LAW IN SOLVING
PROBLEMS OF SUPPLYING
PATIENTS WITH MENTAL HEALTH
PROBLEMS WITH EXTEMPORAL
MEDICINES**

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АБСТРАКТ

The authors conducted review of the scientific literature on the prevalence of mental disorders in the world and in Kharkiv region. There were studied some examples of forensic pharmacy practice regarding improper distribution of medicines, including extemporaneous formulations, to patients suffering from mental health disorders. Based on the research, the authors discuss the problems of providing the eligible for aid patients suffering from mental disorders with extemporaneous medicines, and suggest making appropriate amendments to the normative documents. The authors draw a conclusion that the pharmaceutical law principles contribute to solving the problem of providing patients with mental health disorders with extemporaneous medicines by using the extemporaneous preparations made in pharmacies.

Key words: pharmaceutical law; mental disorders; patients; extemporal medicines.

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**ПРИНЦИПЫ ФАРМАЦЕВТИЧЕСКОГО
ПРАВА В РЕШЕНИИ ПРОБЛЕМЫ
ОБЕСПЕЧЕНИЯ ЭКСТЕМПОРАЛЬНЫМИ
ЛЕКАРСТВЕННЫМИ СРЕДСТВАМИ
БОЛЬНЫХ С ПСИХИЧЕСКИМИ
РАССТРОЙСТВАМИ ЗДОРОВЬЯ**

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Аннотация

Авторами статьи проведен обзор научной литературы относительно распространенности психических расстройств в странах мира и в Харьковском регионе. Изучены примеры из судебно-фармацевтической практики относительно ненадлежащего обеспечения лекарственными средствами, в частности экстремпоральной рецептурой, больных с психическими расстройствами здоровья. На основе проведенного исследования проработаны проблемные вопросы обеспечения больных с психическими расстройствами, которые являются льготным контингентом, экстремпоральными лекарственными средствами, для чего предложено внесение соответствующих изменений в нормативные документы. Установлено, что именно принципы фармацевтического права способствуют решению проблемы обеспечения экстремпоральными лекарственными средствами больных с психическими расстройствами здоровья путем применения врачами экстремпоральных лекарственных средств, изготовленных в условиях аптеки.

Ключевые слова: фармацевтическое право; психические расстройства; больные; экстремпоральные лекарственные средства.

INTRODUCTION. Due to the high informational, psychological and emotional load on society there is an increased incidence of mental illness that require improvement of the efficiency of healthcare and improved legal relationships in the “doctor – patient – pharmacist” system [4, 8, 9, 14, 18, 20].

There are also the growth and scaling up of the industrial accidents in the world, including Japan, Ukraine, the European Union (EU), natural and everyday disasters that have serious medical and social, medical, pharmaceutical, criminal and penal consequences [2, 5, 11].

Aiming at the prevention of major accidents involving dangerous substances and in order to limit their social and environmental impacts that cause mental health problems over the population, the EU adopted Directive 96/82/EU, which requires technicians to apply it to objects where the number of dangerous substances exceed certain thresholds [6]. In addition, the integration of Ukraine into the EU requires harmonization of national legislation and legal acts to EU directives that establish standards of medical and pharmaceutical provision for the population [21, 22, 26].

Materials and methods of the research. The materials of the study included the EU Directives, legislation and regulations of Ukraine; the complaints received on the telephone hotline of the Department of Healthcare of Kharkiv Regional State Administration; the examples from the forensic and pharmaceutical practice; the sources of scientific literature; the Internet sites; the processed extemporal medicines stocks issued by doctors in public healthcare facilities. To achieve this goal, there were used generally accepted methods including legal, documentary analysis, forensic and pharmaceutical monitoring, graphical and tabular methods of analysis.

Results of the research. According to the official WHO statistics, mental illness affects about 450 million people, the most workable of the population, of which 10% are elderly people [17]. According to the research conducted by the government enterprise “The Institute of Neurology, Psychiatry and Addiction” led by academic Voloshin P.V., every third person in the world suffers from various mental health disorders according to ICD-10, whose share in the economically and industrially developed EU countries is 82.8% in Eastern European countries (including

Ukraine) – 88.4%, in the Russian Federation – 86.7%, in developing countries – 65.3%.

The prevalence of mental disorders in the EU is 15.0% of the total population; United States – 38%; Australia – 14.8% [15, 16]. According to forecast by the WHO, in 2020 in European countries mental health disorders will double [12, 13].

WHO data show that at the beginning of 2013:

- 450 million of the citizens around the world suffer from varying degrees of mental illness;

- At least one person suffers from mental disorder from each 4th family in the world;

- People that suffer from mental illness end their lives by suicides in 15-20%;

- 1% of the population suffers from schizophrenia;

- Mental disorders are found in 5% of children in developing countries and in 0.5% of children in developed countries;

- In Europe, each family with four teens has mental illness or abnormalities in mental health.

The review of the scientific literature revealed that mental disorders – disorders of mental activity were established in accordance with the current in Ukraine ICD-10, injuries and causes of death. Mental health problems are common to all countries because more than 25% of the world’s population at some point in their lives suffer from one or more mental disorder. In 1998, the WHO initiated the “Mental health in the world 2000”, which was proposed in 28 countries of the world with epidemiological studies of mental health [17, 27, 28]. Other countries are those where similar research was never carried out, including Ukraine. Describing the social consequences of mental disorders, we need to note a reduced life expectancy of people with mental disorders (when compared with those who do not have them), social exclusion and suicidal behavior that accompany this pathology, a significant deterioration in the quality of life of patients and their relatives. According to the WHO, mental disorders are the third of disabling conditions that lead to reduced life expectancy by an average of 10 years [20]. Effective cooperation in the primary care levels is an essential condition for effective implementation of the measures of psychosocial rehabilitation as an ultimate goal of re-socialization of patients’ recovery or formation of social autonomy, independent functioning in society, expansion of social networks [1, 7].

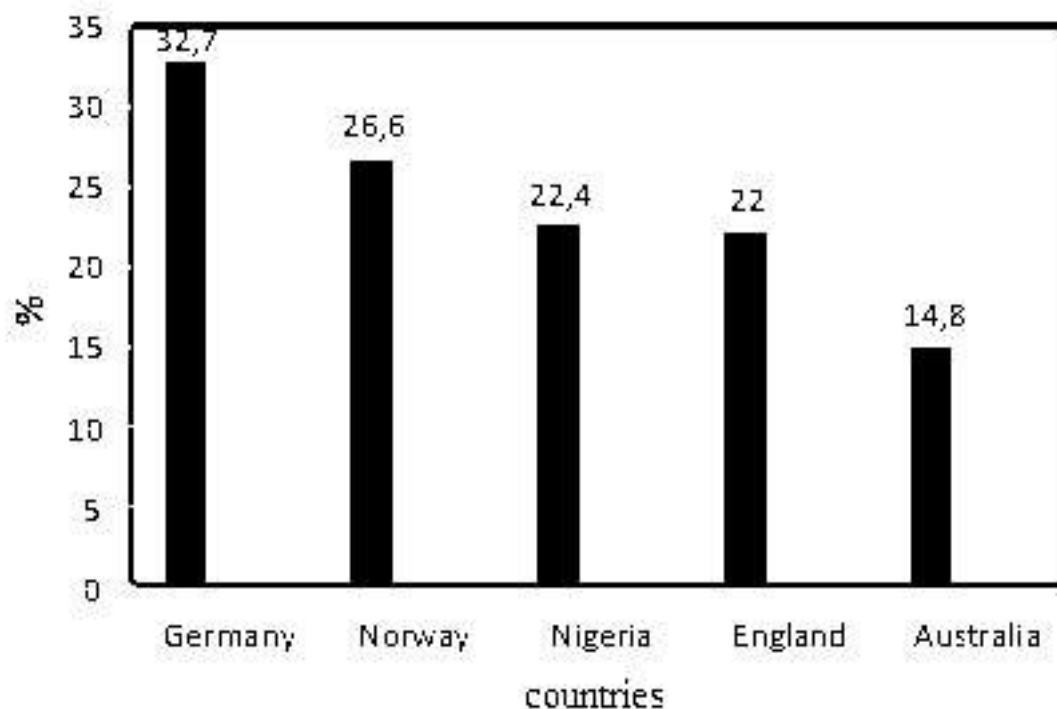


Fig. 1. The incidence of mental disorders in the world

Рис. 1. Распространенность психических расстройств в мире

As shown in Fig. 1, the prevalence of mental health problems is from 14.8% to 32.7% in gross morbidity in the world. Studies show that Ukraine is one of the European countries where there were serious problems in the prevention of the causes and conditions that lead to the development of mental disorders – almost 2 million of Ukrainians annually become psychiatric patients [15, 16]. It was found that in Ukraine, the prevalence of mental disorders is 10 times less than in Western Europe (24% of the population suffers from mental disorders). It is anticipated that by 2020, mental illness will enter the global top five disease-leaders and their share of all diseases could reach 50%. Therefore, the efforts of researchers around the world aimed at prevention of mental illness. The world's leading scientists Sahakyan Barbara and Thomas Insel encourage the new approaches in the development of drugs to treat mental illness. They emphasize the acute shortage of new treatments for mental disorders, including Alzheimer's disease, depression, neurosis and schizophrenia [12]. In turn, I. Pinchuk said that reforming the system of mental healthcare in healthcare professionals of the Ministry of Healthcare of Ukraine requires the following measures to [14]:

- To ensure the institutional and legal framework to provide modern mental healthcare in health facilities;
- To eliminate the effects of abuse by the psychoactive substances when providing mental healthcare;
- Restoration of the rights of people, citizens and patients by granting them psychiatric and pharmaceutical care in mental health care facilities;
- Solving the availability of the medicines to the privileged contingent of patients with preferential discounted prescriptions and improve relationships in the chain “doctor – patient – pharmacist” in providing an individual approach to the manufacturing of the extemporal medicines.

The modern problems of psychogenic disorders caused by subjectively significant adverse events, according to N.A. Maruta, are relevant to the clinical practice and the development of the theory of the medical and pharmaceutical law, which requires a further study of the impact factors of modern psychological trauma in clinical and psychopathic structure of the dissociative disorders on the principles of medical law [9].

The next line of research is aimed at the study of the prevalence of mental disorders in Kharkiv Region. To do this, the authors processed statistical data for the period of 2012-2013, show-

ing that there is a trend following prevalence of mental disorders at the regional level [15, 16, 17] (Table. 1).

Table 1

**The incidence of mental disorders in Kharkiv Region
in 2012-2013 (thousand people)**

Таблица 1

**Показатели распространенности психических расстройств
в Харьковской области за 2012-2013 гг. (тыс. чел.)**

Indicator	Year		Dynamics, -/+ , %
	2012	2013	
The prevalence of mental disorders among adults	116209	115195	- 0,87 %
The prevalence of mental disorders among children	14939	14393	-3,65 %
Number of patients who are under medical supervision	116775	115433	-1,15 %

As shown in Table 1, in 2013, there is a 0.87% decrease in the prevalence of mental health disorders among adults which compared to the prevalence of mental disorders among children in 2012 has decreased by 3.65% (compared to 2012). The number of patients under medical observation in 2013 also came to a decrease (by 1.15% compared to 2012).

One of the measures to improve the access of patients to personalized drug therapy is making extemporal medicines in conditions of pharmacies with the aim of providing an individual approach to the individual patient suffering from mental health disorders. Unfortunately, the recent implementation of a hard market mechanism in the activities of pharmacies of communal ownership has led to what is not considered as forensic and pharmaceutical risks. This is the reason for the fact that in Kharkiv Region on 10/01/2014 only 11 of municipal pharmacies are licensed to manufacture extemporal medicines [3], although in 70-80 years of the XX century, in the city of Kharkiv and Kharkiv Region there were 450 such pharmacies. The level of cooperation of relations in the chain "doctor-patient-pharmacist" reacts the pharmacy realities, because

every Sunday pharmacy representatives participated in the "Days of the chief doctor" who performed municipal healthcare institutions. As part of the event pharmacy specialists inform doctors about the possibility of making the extemporal medicines in the pharmacies.

It was found that more and more practitioners in pharmacies raise the question of decreasing the production of extemporal medicines in Ukraine, which is the result of diversification of finished drugs. Thus, in our opinion and the opinion of the leading scientists of Ukraine, namely Tikhonov O.I. Yarnyh T.G., Tolochko V.M., Ponomarenko M.S., Volokh D.S., Gudzenko A.P., Syatynya M.L., Sosin I.K., Trakhtenberg I.M., Voloshin P.V., Gubskiy Y.I., Maruta N.O., Linsky I.V., Minko O.I. and others, the reserves in the manufacture of the extemporal medicines in pharmacies are great, and this is due to the fact that there are more and more violations of the eligible for aid patients' rights, the wholesale and retail prices are not set and enforced by budgets of different levels [10, 19].

Therefore, developing the concept of the extemporal medicines can effectively influence the pharmacokinetic and pharmacody-

dynamic aspects of drug use, including improving the accuracy of dosing [3, 29]. Due to the lack of ready-made medicines and the needed doses of the drug, the patient has to take the medicine in smaller doses [17]. Very often such cases occur in neurology, psychiatry, oncology, addiction therapy, where due to prolonged use of drugs in the implementation of pharmacotherapy the sick constantly require the adjustment of the dose components of the extemporal medicines on rational solution to the problem of individual dosage of the extemporal medicines in patients with mental health disorders [25].

Appeals from the citizens to the hotline of the Department of Healthcare of Kharkiv Regional State Administration is an example of the fact that in healthcare, there is an imperfect supervisory system of providing patients with mental health disorders with drugs relevant to clinical and pharmaceutical, legal and classification nomenclature and legal groups, as evidenced by the following examples of forensic pharmaceutical practice [18, 19, 23, 24].

Example 1. On 09.09.2014, Ms. E. contacted the hotline with complaints about violations of human rights, complaining that her son K., a disabled person of group II, suffering from mental illness is not provided with drugs Halopryl and Azapin at a discount prescription. It was found that one patient received only preferential Tsiklodol drug and Azapin drug suggested at a dose four times less than the prescribed one. He was denied in providing the drug Halopryl. Based on consultation with the doctor, it was suggested to make a combined dosage form using substances Haloperidol (general classification legal group), Dimedrol (potent legal classification group), Azapin (general classification legal group) and Tsiklodol (toxic classification Andlegal group) in the pharmacy.

Example 2. On 24.01.2014, Ms. T. contacted the hotline with complaints about violations of human rights complaining of the unreasonable refusal to provide her son N., born in 1997, a patient with symptomatic epilepsy (frequent polymorphic attacks) with reduced cost drugs Finlepsyn, Depakin-chrono and Di-

phenine that, according to T., is the violation of human rights. As sedative drugs in psychiatric disorders, doctors recommend the use of compounds which include valerian, oregano, hops, cudweed, inula rootstalks and some other herbs. One should note that due to the selected combination of selected components there may be a decrease in the daily weight of an active pharmaceutical ingredient with increased efficiency due to combined drug potentiation of its components.

Example 3. Investigators of the city of Konotop police station of the Ministry of Internal Affairs of Ukraine in Sumy Region immediately opened criminal proceedings under part 2, art. 307, part 2, art. 309, art. 311 and art. 313 of the Criminal Code of Ukraine. During the preliminary investigation, it was found that on 17.10.2014, during search operations in the apartment, the representatives of several police departments in the city of Konotop have detained four members of an organized criminal group, which was equipped with a laboratory identified as a "mini-factory" of illegal circulation (purchase, storage, production) of psychotropic substances. The chief of the criminal group, a 39-year-old man previously convicted for crimes on the art. 307 of the Criminal Code of Ukraine for four years of imprisonment, had formed a criminal group and divided responsibilities between the members. Thus, in a rented apartment, there was organized an underground laboratory for the manufacture of psychoactive substances (surfactants) sold at a price of 300 USD for 1 gram to the trusted clients suffering from mental and neurological disorders. During the search, the police officers found and withdrew, according to the findings of the forensic examination of pharmaceutical laboratory, the equipment for manufacture of surfactants; laboratory glassware (banks, flasks, test tubes, refrigerators, etc.); 2 grams of psychoactive substance amphetamine; precursors. There were several criminological examinations on the case (forensic, pharmaceutical, forensic, forensic and narcological). The criminal group chief, according to the findings of forensic expertise, was registered with a doctor, a psychiatrist, due to a long abuse of psychoactive substances including the drugs produced by himself, and is in need of

psychiatric treatment. The organizer of the criminal group was temporarily detained through a court proceeding. As for the other members of the group, there were selected some other preventive measures. The pre-trial investigation is being carried on.

As the example 3 shows, the violated principles of the pharmaceutical law in the chain of legal relationships “doctor – patient – pharmacist – lawyer” lead to the practice when patients suffering from mental disorders and having no legal access to drugs provided to different groups at discount prescriptions or Form 3 prescriptions, are forced to apply to persons engaged in illegal circulation of the psychoactive substances (amphetamine) due to the disease and pains of various genesis.

The rights of citizens for drug provision (examples 1, 2, 3), including patients with mental disorders who need vital drugs (Haloperidol, Azapin, Tsiklodol, Finlepsyn, Depakin-Chrono and Diphenine) are guaranteed through the pharmaceutical law and by local budgets (formed from the state budget subsidies) under the current Decree of the Cabinet of Ministers of Ukraine of 17.08.1998 №1303 “On regulation of free and concessional dispensing medicines prescribed by doctors in the case of outpatient treatment of certain groups and in certain categories of diseases” [18].

The principles of pharmaceutical law are given in Article 4 of the Law of Ukraine “On Healthcare” and include:

- Recognition of health care as a priority of the state and society, as one of the main factors of survival and development of the people of Ukraine;

- Observance of human and citizens’ rights and freedoms in the field of health, and securing related government guarantees;

- Humanistic orientation, the priority of human values over class, national, group or individual interests, increased medical and social protection of the most vulnerable categories of people;

- Equality of citizens, democracy and accessibility of health care and other services in the health sector;

- Compliance with the objectives and the level of socio-economic and cultural development of society, the scientific validity, logistical and financial security;

- Focus on current standards of health and medical care, a combination of local traditions and achievements of international experience in health care;

- Preventive nature, complex social, environmental and medical approach to healthcare;

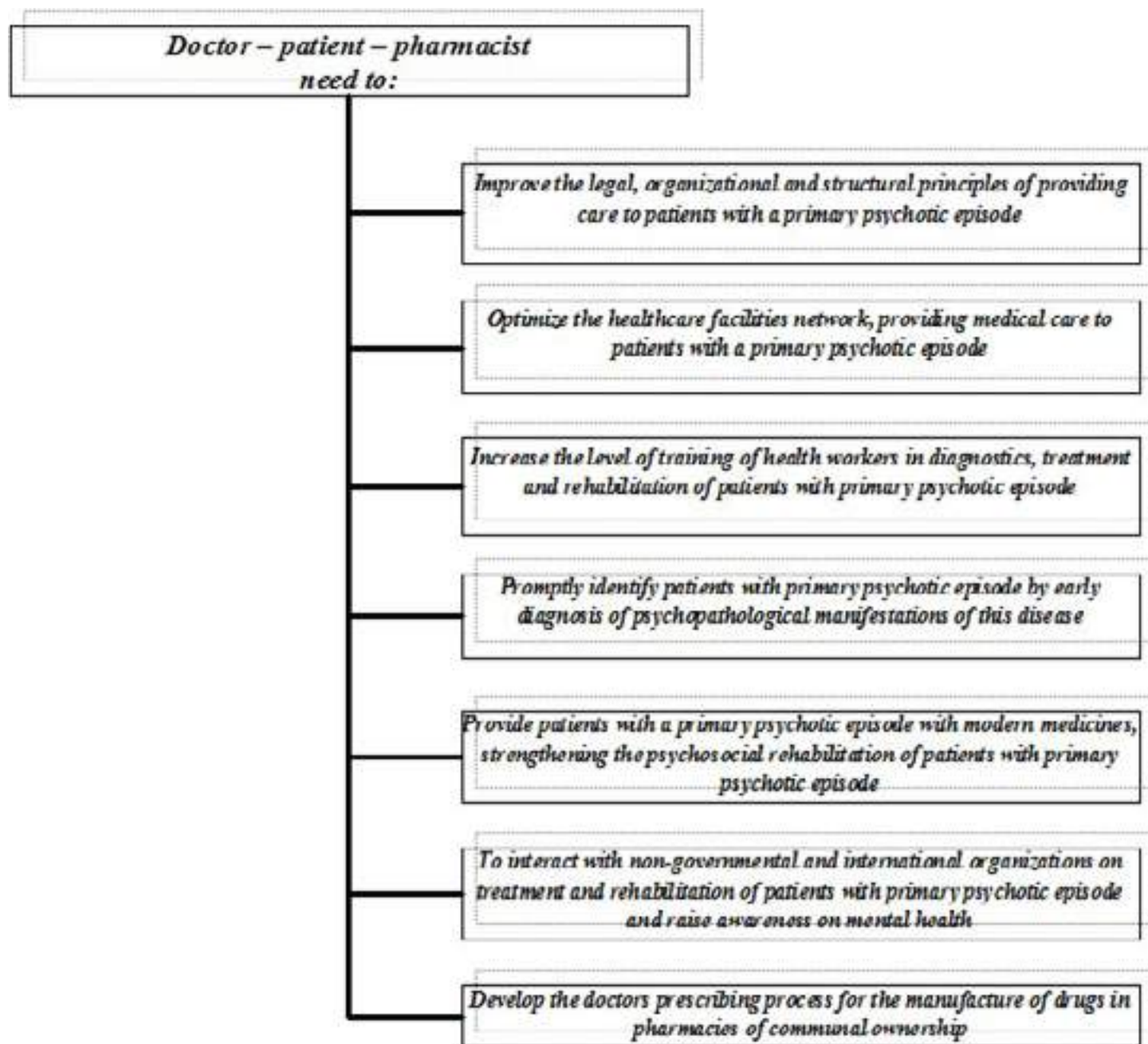
- Stratification of health economics and multi financing of it, the combination of state guarantees monopolization and encouraging entrepreneurship and competition;

- Decentralization of public administration, the development of government institutions and independence of health workers on the legal and contractual basis.

Thus, there is a problem with implementation of the principles laid down in Articles 3 and 49 of the Constitution of Ukraine to provide a preferential contingent of citizens with drugs dispensed at discount prescriptions, namely, Haloperidol, Azapin, Tsiklodol, Finlepsyn, Depakin-Chrono and Biphenyl.

To ensure the patients’ access to the legal system of the extemporal medicines in the “doctor–patient–pharmacist” system there must be resolved the following issues shown in Fig. 2.

CONCLUSIONS. The working group has worked out the proposals received from employees and practical pharmacy patients on the improvement of pharmaceutical legislation with the aim of approaching individual manufacture of extemporal prescriptions based on the individual characteristics of the patient. Thus, there were processed some problematic issues regarding patients with mental disorders belonging to a privileged contingent with finished pharmaceutical products. It was determined that the pharmaceutical law principles contribute to solving this problem the doctors’ use of extemporal medicines made in pharmacies. There were proposed some relevant amendments to the normative documents.



*Fig. 2. The urgent problem areas
in the system of “doctor-patient-pharmacist” relationship*
 Рис. 2. Проблемные вопросы в системе правоотношений
 «врач-пациент-провизор»

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