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**COMPARATIVE ANALYSIS OF AVAILABILITY
OF THE MEDICINES FOR PRIVILEGED
CATEGORIES OF CITIZENS SUFFERING FROM
DIABETES MELLITUS IN THE RUSSIAN
FEDERATION AND UKRAINE BASED ON THE
PHARMACEUTICAL LAW**

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Researched the particularities of the legal field of Ukraine and Russia, which regulates organization rules of the medicines circulation used for the pharmacotherapy of diabetes mellitus. Pharmaceutical law in public administration of Russia and Ukraine is the foundation and guarantor in protecting the rights for the states declared preferential categories of citizens with diabetes to have access to essential medicines. The results of forensic and pharmaceutical practice related to violation of the rights of people with diabetes mellitus to improve the system of state control measures for increasing the availability of medicines for privileged contingent of citizens based on the norms of pharmaceutical law. Shown that the authorized state authorities need to provide scientific advice on the prevention of diabetes mellitus; update, in accordance with European requirements and standards guidelines of diagnosis, clinical protocols and rules of care for patients with diabetes.

Keywords: pharmaceutical law; medicine; diabetes mellitus; preferential population.

World Health Organization (WHO) paid close attention to the timely detection and treatment of diabetes mellitus (DM), since there are more than 382 million people suffering from this disease in the world [1]. In 2004, according to scientists, medical, pharmaceutical, social, and economic consequences of diabetes led to the fact that 3.4 million people died of high blood sugar, the same trend will continue in 2010 with more than 80% of deaths from diabetes occur in low- and middle-income countries [2]. Life expectancy of patients with DM is twice less when compared to their peers who do not suffer health problems and leading a healthy way of life [3].

At the same time the availability of the medicines for privileged categories of citizens, who suffer from diabetes mellitus in the Russian Federation and Ukraine depends on many factors. Some of these factors are improving of the management measures and control over the circulation of medicines (drugs); prevention and disease prevention; the use of personalized pharmacotherapy; ensuring the availability

of essential medicines for privileged categories of citizens. According to Akimov V.A., Bogachev V.J., Vladimirsky V.K., government controls are a set of actions of officials in the relations "doctor - patient suffering from diabetes mellitus and related to the privileged category to ensure drug – pharmacist – supervisory authority – a lawyer" [4].

The aim. To study the particularities of legal documents in Ukraine and Russia, aimed at organizing the rules regulating the circulation of the medicines used for diabetes mellitus pharmacotherapy by generalizing forensic and pharmaceutical practices related to the violation of the rights of patients with diabetes. To improve the system of measures of state control over the increasing availability of medicines for citizens of privileged contingent based on the norms of pharmaceutical law.

Materials and methods of the research. As the imperative material used the legal framework of the of the Russian Federation and Ukraine in the field of healthcare; statistics on the incidence of diabetes mellitus in the Russian Federation, Ukraine and the border areas of the Euroregion "Sloboda" (Belgorod region of the Russian Federation and Ukraine's Kharkiv region); data of the forensic and pharmaceutical practices related to the treatment of citizens from a "hot line" of the Department of Healthcare of Kharkiv Regional State Administration (hospital records, contracts between medical institutions and pharmacies, municipal and other forms of property, and others.); sources of scientific literature; materials on the Internet. Organizational, legal, medical and pharmaceutical researches in ensuring of the privileged categories of citizens suffering from diabetes mellitus, accompanied by the use of the documentary, regulatory, forensic, graphic and pharmaceutical analysis.

Results and discussion. Diabetes mellitus refers to diseases arising from chronic metabolic health disorders due to insufficient insulin hormone in humans [3, 5]. Important to note, that the effects of diabetes mellitus affect the performance of other organs and systems of the human body. For example, diabetes affects the cardiovascular, mental, urinary system, affects blood clotting, visual acuity, hearing, motor responses, and others. In people suffering from diabetes, increases the risk of disease hypertension, myocardial infarction, stroke (50% of patients with diabetes die from cardiovascular disease). To solve this problem Efremov O.A., Kovaleva Yu.A., Shelest B.A. recommend to normalize and continue to monitor the level of lipid metabolism, continuous monitoring of systolic and diastolic blood pressure, as well as used in pharmacotherapy drugs, ACE inhibitors (ramipril) in combination with statins (simvastatin) [6]. Also, it should be noted that due to reduced blood flow and diabetic neuropathy develops in the legs leading to the emergence of ulcers, development of infectious diseases (for wounds, trauma, cuts), which in turn necessitates immediate amputation. We should also point out that diabetic retinopathy is one of the factors leading to

blindness, that is causally related to the long-term accumulated damage to the small blood vessels in the retina of the eye, as well as renal failure [2, 7].

The greatest quantitative distribution of patients with diabetes mellitus in the world [8] are typical for India (50.8 million. pers.), China (43.2

million. pers.), US (26.8 million. pers.), Brazil (7.6 million. pers.), Germany (7.5 million. pers.), Pakistan (7.1 million. pers.), Japan (7.1 million. pers.), Indonesia (7 million. pers.) Mexico (6.8 million. pers.), Russia (3.8 million. pers.), Ukraine (1.3 million. pers.), which is shown on Fig. 1.

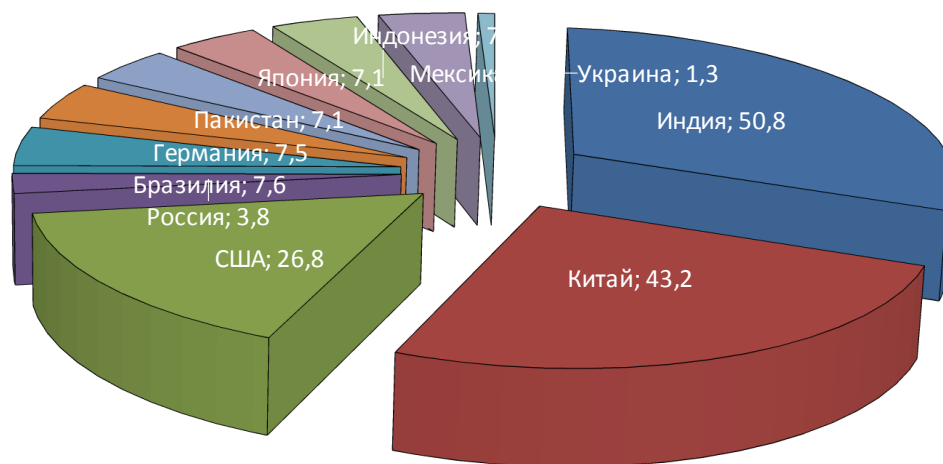


Fig. 1. The number of patients suffering from diabetes mellitus worldwide was 382 million persons as of November 2013 [8]

According to legal documents and clinical protocols of Russia [9] and Ukraine [10] treatment of diabetes mellitus is to lower blood glucose levels, which in patients with type 1 diabetes require insulin medicines (Humodar, Monodar, Aktropid, Protofan and others); for patients with type 2 diabetes – oral drugs (Diabeton, Siofor, Amaryl, Manin, Diaglizid etc.) [9, 10], and if necessary in the course of treatment using insulin. In this crucial moment is the constant monitoring of blood pressure and lipid content in the blood (control cholesterol levels), screening and treatment for retinopathy, as well as the early symptoms of comorbidities [11].

It is important that in the course of treatment and the use of the medicines, each patient led a healthy

life, stick to a diet, regular physical activity, maintain a stable body weight, refused to bad habits (smoking, alcoholism, drug addiction, substance abuse) and ruled stressful and depressive states [11].

The studies found that the prevalence of diabetes in the Russian Federation continues to grow, primarily due to patients with type 2 diabetes, as evidenced by the data of the State Register of measuring instruments. Registered in the Russian Federation as of 2013, there are 3,778,697 diabetic patients (including more than 29,000 children and adolescents), of whom 91% of patients with type 2 diabetes [12-14], of which in the Belgorod region of the Russian Federation, there are 46,820 people (Fig. 2).

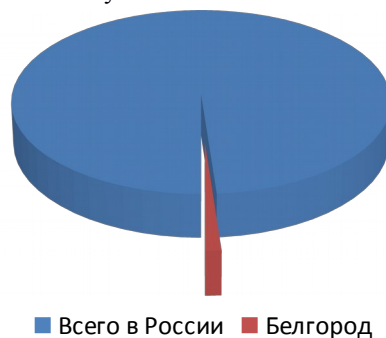


Fig. 2. The proportion of patients with diabetes mellitus type 1 and 2 in the Russian Federation and the Belgorod region of the Russian Federation in 2013 [12-14]

WHO experts in Russia estimated about 12 million patients with diabetes mellitus and include the Russian Federation among the top 10 countries with the

highest number of such persons. It should also be borne in mind that in patients with type 2 diabetes already in the diagnosis of the disease in 40% of cases there are complications. The cost of medical care for patients

with diabetes is 2-3 times higher than patients without diabetes. In 2000, the cost of treating diabetes in Russia estimated at 65.2 billion of the US dollars, of which 10.7 billion of the US dollars were direct costs and 54.5 billion of the US dollars – indirect costs [12].

Ensuring the rights of patients, patients with diabetes mellitus and providing vital medicines of all classification and legal groups, according to Trachtenberg I.M. based solely on the norms of medical and pharmaceutical law, the Constitution and laws of Ukraine. This will enable the government to control the process of the licensing conditions for the implementation of activities related to the trafficking of drugs in health facilities (pharmacies and hospitals). [15, 16] According to Galatsan A.V., Shapovalov V.V., Omelchenko V.A. namely medical and pharmaceutical

law is a basic system for control of the medicines circulation, which are released at discounted prescription (Diabeton, Siofor, Amaryl) in healthcare facilities and pharmacies that have appropriate agreements to provide preferential categories of the population in the system of legal drugs "doctor – preferential patient – pharmacist" [17, 18].

Based on comparative analysis found that the number of diabetic patients who are registered in Ukraine is 1311335 people, including the territory of the Kharkiv region is home to 86,774 people (Fig. 3). Analysis of the prevalence of disease in the diabetic population in the Kharkov region for the period from 2012 to 2013 indicates that the observed dynamics of growth (3%) [19].

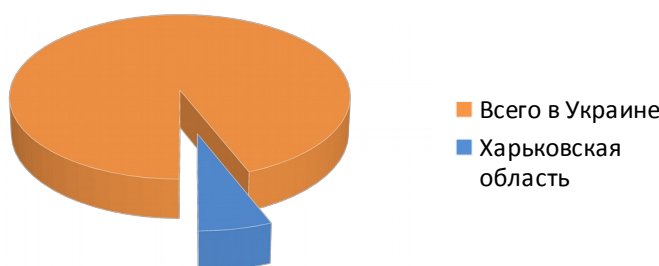


Fig. 3. The proportion of patients with diabetes mellitus in Ukraine and the Kharkiv region of Ukraine in 2013 [19]

Taking into account that the funding of the state program "Diabetes" [13] is carried out centrally by the Ministry of Healthcare of Ukraine, which makes the tender purchases, controls medicines circulation and transfer them to the public health institutions in which drugs prescribed by law are released each patient personally (only standing on the dispensary). At the same time in parallel, carried out to ensure drug people suffering from diabetes, at the expense of local budgets, which is regulated by the Cabinet of Ministers of Ukraine of 17.08.1998 №1303 "On regulation of free and concessional dispensing on prescription in outpatient treatment of certain groups of the population and certain categories of diseases" [20].

Based on the statistical data shows that 80% of patients on diabetes live in countries with a low standard of living. The dynamics of diabetes considered not only as a serious disease, but also as an important medical and pharmaceutical, social, economic and criminal legal problem, which is now very important for Russia, Ukraine and other countries of the world. This is because there is a constant increase in the number of patients suffering from diabetes on, with chronic diseases, the development of micro- and macrovascular complications, which lead to a reduction in life expectancy due to deterioration of its quality [1, 21].

However, as the forensic and pharmaceutical analysis shows from the practice of forensic and criminal violations that take place in Ukraine [12, 22-25] and Russia [18, 26, 27] on the part of officials of the tender regulations in relation to the centralized procurement of the medicines, as evidenced by the law enforcement agencies registered criminal cases, appeals

and complaints by citizens concerning the violations of their rights to access to the medicines. Forensic and pharmaceutical practice shows that in Ukraine there is a tendency of violating human patients suffering from diabetes and low-income (pensions, salaries), on free access to discounted medical and pharmaceutical care, which leads to poor health and criteria forensic evaluation to moderate and severe personal injury. These facts are signs of criminal offenses provided for in Articles 140, 368 of the Criminal Code of Ukraine (the patient unreasonably denied free access to concessional (free) drugs, due to low incomes, it is unable to buy expensive drugs, which causes a sharp deterioration in the health and development of related diseases.

Based on the analysis and systematization of patient suffering from diabetes mellitus, during 2014 a "hot line" of the Department of Healthcare of Kharkiv Regional State Administration revealed that 60% of complaints related to low availability issues for privileged categories of citizens, patients with diabetes, to the medicines. When generalizing investigated complaints and appeals on social grounds found that increasingly turning: the elderly (over 50 years) – 85%, with women accounting for 60%, and men – 40%. Place of residence: 70% of patients are residents of Kharkiv region and 30% – in Kharkiv. Generalization of complaints regarding free provision of necessary medicines at discounted prescription carried out in a three-tier system of relations.

Established that on the first level in system of legal the relations "doctor – grace patient with diabetes" recorded 15.0% of complaints, of which typical are these: 1) failure of the doctor to write a prescription

discount to patients suffering from diabetes; 2) prescription of doctors preferential recipes for drugs that are not purchased for the budget (due to excess registered by the Ministry of Healthcare of Ukraine wholesale prices); 3) prescription of doctors preferential recipes for medicines from other manufacturers for patients suffering from diabetes.

On the second level in the system of legal relations "grace patient suffering from diabetes mellitus – pharmacist" recorded 25.0% of applications, typical of which are as follows: 1) a significant temporary undue delay release of the medicines at discounted prescription; 2) failure to provide preferential medicines for patients suffering from diabetes mellitus; 3) incorrect behavior of pharmaceutical worker while ensuring the availability of drugs for concessional patients suffering from diabetes.

On the third level in the system of legal relations "doctor – specialist" were more than just complaints and appeals (60.0%) from patients, that suffer from the diabetes mellitus, like: 1) the debt payment from medical institutions on secured by preferential pharmacy prescriptions; 2) inconsistencies between physicians and pharmacists on the list of drugs for patients with diabetes who can write at discounted prescriptions.

The results of the forensic and pharmaceutical monitoring of complaints and appeals of citizens indicate that the availability of the necessary drugs at discounted prescriptions for patients suffering from diabetes, not provided in full. One reason for this is the increase in financial expenses due to the increase in the cost of pharmacotherapy drugs and the number of privileged categories of citizens suffering from diabetes. Among the conditions necessary to ensure the grace of patients with diabetes mellitus should be noted on the official finding dispensary that will provide them with the rights and guarantees of access to health care and receive free drugs.

Conclusion

Researched the particularities of legal documents in Ukraine and Russia, aimed at organizing rules regulating trafficking drugs used in the pharmacotherapy of diabetes. Found that pharmaceutical law in the field of public administration in Russia and Ukraine is the foundation and guarantor in protecting the rights of states declared the privileged category of people suffering from diabetes mellitus, on unrestricted access to essential drugs.

The results of forensic and pharmaceutical practice related to the violation of the rights of patients with diabetes mellitus to improve the system of measures of state control over the increasing availability of medicines for privileged contingent of citizens of Ukraine based on the norms of pharmaceutical law.

Established that the Ministry of Healthcare of Ukraine and the Russian Ministry of Healthcare must provide scientific advice for the prevention of diabetes mellitus; update in accordance to the European standards and directives, standards of diagnosis, clinical protocols and rules of care for patients suffering from

diabetes mellitus; raise public awareness about the global epidemic of diabetes; analyze forensic and pharmaceutical practice as a result of violations of the rights of patients with diabetes to ensure preferential (free) drugs.

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COMPARATIVE ANALYSIS OF AVAILABILITY OF THE MEDICINES FOR PRIVILEGED CATEGORIES OF CITIZENS SUFFERING FROM DIABETES MELLITUS IN THE RUSSIAN FEDERATION AND UKRAINE BASED ON THE PHARMACEUTICAL LAW

Shapovalov V.V. (Jr), Shapovalova V.A., Shapovalov V.V., Rogozhnykova O.V.

World Health Organization paid close attention to the timely detection and treatment of diabetes mellitus, since there are more than 382 million people suffering from this disease in the world. Life expectancy of patients with diabetes mellitus is twice as less when compared to their peers who do not suffer health problems and leading a healthy way of life. Based on the statistical data shows that 80% of patients on diabetes live in countries with a low standard of living. The dynamics of diabetes considered not only as a serious disease, but also as an important medical and pharmaceutical, social, economic and criminal legal problem, which is now very important for the Russian Federation, Ukraine and other countries of the world. This is because there is a constant increase in the number of patients suffering from diabetes on, with chronic diseases, the development of micro- and macrovascular complications, which lead to a reduction in life expectancy due to deterioration of its quality. At the same time the availability of the medicines for privileged categories of citizens, who suffer from diabetes mellitus in the Russian Federation and Ukraine depends on many factors. Some of these factors are improving of the management measures and control over the circulation of medicines (drugs); prevention and disease prevention; the use of personalized pharmacotherapy; ensuring the availability of essential medicines for privileged categories of citizens. Therefore, the aim of the work was to study the particularities of legal documents in Ukraine and Russia, aimed at organizing the rules regulating the circulation of the medicines used for diabetes mellitus pharmacotherapy by generalizing forensic and pharmaceutical practices related to the violation of the rights of patients with diabetes. To improve the system of measures of state control over the increasing availability of medicines for citizens of privileged

contingent based on the norms of pharmaceutical law. In the study researched the particularities of legal documents in the Ukraine and Russian Federation aimed at organizing rules regulating circulation of the drugs used in the pharmacotherapy of diabetes. Found that pharmaceutical law in the field of public administration in the Russian Federation and Ukraine is the foundation and guarantor in protecting the rights of states declared the privileged category of people suffering from diabetes mellitus on unrestricted access to essential drugs. Established that the Ministry of Healthcare of Ukraine and the Ministry of Healthcare of Russian Federation must provide scientific advice for the prevention of diabetes mellitus; update in accordance to the European standards and directives, standards of diagnosis, clinical protocols and rules of care for patients suffering from diabetes mellitus; raise public awareness about the global epidemic of diabetes; analyze forensic and pharmaceutical practice as a result of violations of the rights of patients with diabetes to ensure preferential (free) drugs. Ensuring the rights of patients with diabetes mellitus and providing vital medicines of all classification and legal groups, should base solely on the norms of medical and pharmaceutical law, the Constitution and laws of Ukraine. This will enable to the government to control the process of the licensing conditions for the implementation of activities related to the circulation of drugs among the healthcare facilities (pharmacies and hospitals).

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**СРАВНИТЕЛЬНЫЙ АНАЛИЗ ДОСТУПНОСТИ
ЛЕКАРСТВЕННЫХ СРЕДСТВ ДЛЯ
ЛЬГОТНЫХ КАТЕГОРИЙ ГРАЖДАН,
СТРАДАЮЩИХ САХАРНЫМ ДИАБЕТОМ В
РОССИЙСКОЙ ФЕДЕРАЦИИ И УКРАИНЕ НА
ОСНОВЕ ФАРМАЦЕВТИЧЕСКОГО ПРАВА**

**Шаповалов В.В. (мл.), Шаповалова В.А.,
Шаповалов В.В., Рогожникова О.В.**

Всемирной Организацией Здравоохранения уделяется пристальное внимание вопросам своевременного выявления и лечения сахарного диабета, поскольку в мире насчитывается более 382 млн. человек, страдающих данным заболеванием. Исходя из статистических данных видно, что 80% больных сахарным диабетом проживают в странах с низким уровнем жизни. Динамика заболеваемости позволяет рассматривать сахарный диабет не только как серьезное заболевание, но и как важную медико-фармацевтическую, социально-экономическую и уголовно-правовую проблему, которая сегодня очень актуальна для России, Украины и других стран мира. Это связано, с тем что происходит постоянное увеличение количества пациентов страдающих сахарным диабетом, при этом хронический характер заболевания, развитие микро- и макрососудистых осложнений, которые приводят к сокращению продолжительности жизни при ухудшении ее качества. В то же время доступность оборота необходимых лекарственных средств для больных сахарным диабетом зависит от многих факторов,

среди которых: совершенствование мер управления и контроля за оборотом лекарственных средств; профилактика и предупреждение заболеваний; применение персонализированной фармакотерапии; обеспечение доступности оборота жизненно важных лекарственных средств для льготных категорий граждан.

Поэтому целью работы было изучить особенности нормативно-правовых документов Украины и России, направленные на организацию регулирования правил оборота лекарственных средств, используемых для фармакотерапии сахарного диабета путем обобщения судебно-фармацевтической практики, связанной с нарушением прав больных сахарным диабетом, для совершенствования системы мер государственного контроля за повышением доступности медикаментов для льготного контингента граждан на основе норм фармацевтического права.

В ходе исследования изучены нормативно-правовые документы Украины и России, направленные на организацию регулирования правил оборота лекарственных средств, используемых для фармакотерапии сахарного диабета. Выяснено, что фармацевтическое право в сфере государственного управления России и Украины является базовой основой и гарантом в защите задекларированных государствами прав льготной категории граждан, страдающих сахарным диабетом, на неограниченный доступ к жизненно необходимым лекарственным средствам. Установлено, что Министерство здравоохранения Украины и Министерство здравоохранения России необходимо предоставлять научные рекомендации по предупреждению сахарного диабета; обновлять, в соответствии с европейскими требованиями и директивами, стандарты диагностики, клинические протоколы и правила ухода за пациентами, страдающими сахарным диабетом; повышать уровень информированности населения о глобальной эпидемии сахарным диабетом; анализировать судебно-фармацевтическую практику вследствие нарушений прав пациентов с сахарным диабетом на обеспечение льготными (бесплатными) лекарственными средствами. Обеспечение прав пациентов, больных сахарным диабетом, и их обеспечение жизненно необходимыми лекарственными средствами всех классификационно-правовых групп должно базироваться исключительно на нормах медицинского и фармацевтического права, Конституции Украины, Законах Украины. Это даст возможность государству контролировать процесс выполнения лицензионных условий по внедрению деятельности, связанной с оборотом лекарственных средств в учреждениях охраны здоровья (аптеках и больницах).

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**ПОРІВНЯЛЬНИЙ АНАЛІЗ ДОСТУПНОСТІ
ЛІКАРСЬКИХ ЗАСОБІВ ДЛЯ ПІЛЬГОВИХ**

КАТЕГОРІЙ ГРОМАДЯН, ЩО СТРАЖДАЮТЬ ЦУКРОВИМ ДІАБЕТОМ В РОСІЙСЬКІЙ ФЕДЕРАЦІЇ ТА УКРАЇНІ НА ОСНОВІ ФАРМАЦЕВТИЧНОГО ПРАВА

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Всесвітньою Організацією Охорони Здоров'я приділяється пильна увага питанням своєчасного виявлення та лікування цукрового діабету, оскільки у світі налічується понад 382 млн. осіб, які страждають даним захворюванням. Виходячи зі статистичних даних видно, що 80% хворих на цукровий діабет проживають в країнах з низьким рівнем життя. Динаміка захворюваності дозволяє розглядати цукровий діабет не тільки як серйозне захворювання, але і як важливу медико-фармацевтичну, соціально-економічну та кримінально-правову проблему, яка на сьогодні є дуже актуальною для Росії, України і інших країн світу. Це пов'язано, з тим що відбувається постійне збільшення кількості пацієнтів, які страждають на цукровий діабет, при цьому хронічний характер захворювання, розвиток мікро- і макросудинних ускладнень, які призводять до скорочення тривалості життя при погіршенні її якості. У той же час доступність обігу необхідних лікарських засобів для хворих на цукровий діабет залежить від багатьох факторів, серед яких: вдосконалення заходів управління і контролю за обігом лікарських засобів; профілактика та попередження захворювань; застосування Персоналізація фармакотерапії; забезпечення доступності обороту життєво важливих лікарських засобів для пільгових категорій громадян. Тому метою роботи було вивчити особливості нормативно-правових документів України та Росії, спрямовані на організацію регулювання правил обігу лікарських засобів, що використовуються для фармакотерапії цукрового діабету шляхом узагальнення судово-фармацевтичної практики, пов'язаної з порушенням прав хворих на цукровий діабет, для вдосконалення системи заходів державного контролю за підвищенням доступності медикаментів для пільгового контингенту громадян на основі норм фармацевтичного права. У ході дослідження вивчені нормативно-правові документи України і Росії, спрямовані на організацію регулювання правил обігу лікарських засобів, що використовуються для фармакотерапії цукрового діабету. З'ясовано, що фармацевтичне право у сфері державного управління Росії і України є базовою основою і гарантом у захисті задекларованих державами прав пільгової категорії громадян, які страждають на цукровий діабет, на необмежений доступ до життєво необхідних лікарських засобів. Встановлено, що Міністерство охорони здоров'я України та Міністерство охорони здоров'я Росії необхідно надавати наукові рекомендації щодо попередження цукрового діабету; оновлювати, відповідно до європейських вимог і директивами, стандарти діагностики, клінічні протоколи та правила догляду за пацієнтами, що страждають на цукровий діабет;

підвищувати рівень інформованості населення про глобальну епідемію цукровий діабет; аналізувати судово-фармацевтичну практику внаслідок порушень прав пацієнтів з цукровим діабетом на забезпечення пільговими (безкоштовними) лікарськими засобами. Забезпечення прав пацієнтів, хворих на цукровий діабет, та їх забезпечення життєво необхідними лікарськими засобами всіх класифікаційно-правових груп має базуватися виключно на нормах медичного та фармацевтичного права, Конституції України, Законах України. Це дасть можливість державі контролювати процес виконання ліцензійних умов щодо впровадження діяльності, пов'язаної з обігом лікарських засобів в установах охорони здоров'я (аптеках і лікарнях).