DOI: 10.22394/2070-8378-2018-20-2-93-96

Подготовка юристов для медицинского и фармацевтического рынков России

АЛЕКСАНДР АНАТОЛЬЕВИЧ МОХОВ, **доктор юридических наук, профессор кафедры предпринимательского и корпоративного права**
Московский государственный юридический университет имени О.Е. Кутафина (МГЮА) (123995, Российская Федерация, Москва, ул. Садовая-Кудринская, 9). E-mail: mokhov_alexander@rambler.ru

Аннотация: Рыночные преобразования, проводимые в России, привели к формированию и развитию новых видов и сфер экономической деятельности, новых рынков, новых видов услуг. Наиболее динамично развивающимися в современной России являются рынок медицинских услуг, а также фармацевтический рынок. Огромный их потенциал в России привлекает к ним все новых и новых экономических агентов, в том числе и недобросовестных, что не может не учитываться законодателем и правоприменителем.

В последнее десятилетие идет активный процесс формирования и развития законодательства, регулирующего вопросы охраны здоровья граждан, здравоохранения, обращения лекарственных средств и иных товаров для здоровья. Это важно для надлежащего правового обеспечения деятельности хозяйствующих субъектов на данных рынках, а также управления сферой здравоохранения. Кроме того, принимаемые акты в отношении медицины и фармацевтики способствуют устранению рисков для здоровья граждан, позволяют эффективно управлять бизнесом, регулировать рынки медицинских услуг и фармацевтики на наднациональном, национальном и региональном уровнях. Сегодня существует насущная потребность в подготовке юристов, способных к решению задач, связанных с функционированием этих рынков. В статье анализируется образовательная деятельность высших учебных заведений Российской Федерации по этим направлениям.

Автор отмечает, что в ряде зарубежных стран (в первую очередь, в тех, где получили хорошее развитие медицина и фармацевтика, медицинская и фармацевтическая наука) термины «медицинское право» и «фармацевтическое право» являются давно устоявшимися.

Ключевые слова: рынок, правовое государство, экономика, отрасль

Статья поступила в редакцию 7 декабря 2017 года.

Мохов А.А. Подготовка юристов для медицинского и фармацевтического рынков России. *Государственная служба*. 2018. № 2. С. 93–96.

TRAINING LAWYERS FOR MEDICAL AND PHARMACEUTICAL MARKETS IN RUSSIA

ALEXANDER A. MOKHOV, **Doctor of Law, Professor of the Department of Entrepreneurial and Corporate Law**
Kutafin Moscow State Law University (MSAL) (9 Sadovaya-Kudrinskaya Street, Moscow, Russian Federation, 123995). E-mail: mokhov_alexander@rambler.ru

Abstract: Market transformations in Russia have led to the formation and development of new types and spheres of economic activity, new markets, and new types of services. The most dynamically developing markets in modern Russia are the market for medical services and the pharmaceutical market. The huge potential of medical and pharmaceutical markets in Russia attracts more and more new economic agents to them, including dishonest ones, which cannot be ignored by the legislation and law enforcement. In connection with the abovementioned, over the last decade, an active process has been underway to formulate and develop legislation that regulates the issues of protecting citizens' health, public health, circulation of medicaments and other health products. The abovementioned causes the need for proper legal support for the activities of economic entities in these markets, as well as for health sector management. Without organizing the legal work in the field of "medicine and pharmaceuticals" in modern conditions, it is impossible to level out emerging legal risks in these markets, effectively manage business, regulate these markets at supranational, national and regional levels. In connection with everything mentioned above, today there is an urgent need for training lawyers who are capable of solving problems connected with medical and pharmaceutical markets. The article describes the current situation in Russian higher education institutions regarding these directions of legal training.

The author notes that in a number of foreign countries (first of all, in those where medicine and pharmaceuticals, medical and pharmaceutical science gained strong development) the terms 'medical law' and 'pharmaceutical law' are long-established.
Keywords: market, law-based state, economy, branch

Mokhov A.A. Training lawyers for medical and pharmaceutical markets in Russia. *Gosudarstvennaya sluzhba*. 2018. № 2. P. 93–96. In Russian

Introduction

Market transformations in Russia have led to the formation and development of new types and spheres of economic activity, new markets, and new types of services. In a constitutional state, which our country is, according to the Part 1 Art. 1 of the Constitution of the Russian Federation, the impact on the economy as a whole, its separate branches and sectors, should be carried out in the legal form in strict compliance with the current legislation.

The most dynamically developing markets in modern Russia are the market for medical services and the pharmaceutical market. This trend is quite natural: on the whole, for countries that have moved from the so-called administrative-command economy to the market economy, the rapid development of medical services markets is associated with the development of private healthcare, as well as involvement in the provision of health services and the public health sector; the world and national pharmaceutical markets are growing due to the active supply of healthcare and the population with new innovative products, meeting the existing needs and demands for health products.

The huge potential of medical and pharmaceutical markets in Russia attracts more and more new economic agents to them, including dishonest ones, which cannot be ignored by the legislation and law enforcement. In addition, many of their services, works, and goods circulating in these markets are classified as socially significant, and to some extent ensure the national security of the state.

In connection with the abovementioned, over the last decade, an active process has been underway to formulate and develop legislation that regulates the issues of protecting citizens' health, public health, circulation of medicaments and other health products. Currently, about two dozen special federal laws and thousands of legal acts have been adopted, which regulate the most important social relations in the spheres of economic activity in question.

Legal support for medical and pharmaceutical markets

The formation of the Eurasian Economic Union should, in the near future, lead to the harmonization or even unification of a number of markets, including markets for medical services, medicaments, and some other goods. In this regard, along with the national appears supranational regulation, which cannot be ignored by the subjects of the medical and pharmaceutical markets, as well as lawyers engaged in legal support of businesses.

The abovementioned causes the need for proper legal support for the activities of economic entities in these markets, as well as for health sector management. Without organizing the legal work in the field of "medicine and pharmaceuticals" in modern conditions, it is impossible to level out emerging legal risks in these markets, effectively manage business, regulate these markets at supranational, national and regional levels.

In connection with everything mentioned above, today there is an urgent need for training lawyers who are capable of solving such problems as legal protection of health and life of citizens; ensuring the legality in the implementation of medical and pharmaceutical activities; protection of rights and legitimate interests of economic entities in the market of medical services and the pharmaceutical market; providing legal assistance, advising stakeholders on the legal regulation of medical and pharmaceutical activities; implementation of legal expertise of regulatory legal acts in the field of medicine, public health, circulation of medicines and other means of medical application; implementation of organizational and management functions in the field of medicine, public health, and pharmaceuticals; carrying out scientific researches on legal problems of legal regulation of medical and pharmaceutical activity.

Law education in the fields of medical and pharmaceutical markets

What curriculum and courses do we have now? Are they able to create the necessary competencies for lawyers, prepare them for work on the medical and (or) pharmaceutical markets?

The list of disciplines that are obligatory for students studying at law schools and faculties that are closest to questions of the right regulation of the economy (civil law, business law, civil and arbitration process, etc.) shows that they are incapable of forming the competencies necessary for these markets. This is evidenced both by the results of the conducted tests, and the results of interviews conducted among law students, as well as opinions of industry experts.

So it turned out that special sets of legislation (not only applied to medicine and pharmaceuticals, but also to other spheres of economic activity) by students are either not studied at all, or are studied "on a residual principle". There are objective and subjective reasons for this. Among the main ones one should mention: the presence of fairly "rigid" federal state educational standards that do not allow active and timely curriculum update, introduction of new disciplines and courses; transition to multi-level training of legal personnel (bachelor's, master's); conservatism of legal education; insufficient attention of state regulators in this sphere to issues of legal support, legal support of medical and pharmaceutical activities; a number of theoretical and methodological problems [Blazheev, Svistunov, 2011].

Despite the existing problems, positive tendencies have recently emerged: new, more flexible educational standards have just been adopted; practice oriented educational technologies are introduced; new academic disciplines and courses are being developed; there is an adaptation of the nomenclature of scientific specialties taking into account modern trends in the development of law, the needs of a market economy. [Matskevich, Vlasenko, 2013]. In some universities, attempts are being made to introduce such training courses as competition law,

commercial law, corporate law, transport law, sports law, energy law, etc. This approach seems to be correct, as in other long-established disciplines it is extremely difficult to explore comprehensively and consistently new subject fields, and especially to form new competencies.

The existing needs for training lawyers for the domestic medical and pharmaceutical markets can be solved by introducing in the educational process such disciplines as medical law and pharmaceutical law.

Names of educational disciplines are debatable. Instead of medical law in the literature they are also called: health law, biomedical law, etc. [Maleina, 2013; Sergeev, 2006]. Regarding pharmaceutical law, there is no meaningful discussion.

Definition of "medical law" and "pharmaceutical law"

It should be noted that in a number of foreign countries (first of all, in those, where medicine and pharmaceuticals, as well as medical and pharmaceutical science have developed well), the terms "medical law" and "pharmaceutical law" are long established.

In our country, the question of teaching medical law to lawyers has been put up for a long time [Mokhov, 2003], but until recently there has been no widespread application of this discipline in lawyers' training. Only some law schools and faculties can offer such discipline to their students. Examples are Kutafin Moscow State Law University, the School of Law in St. Petersburg State University, the Saratov State Law Academy, the Law Institute of Volgograd State University, the School of Law in Penza State University, and some others.

At the same time, this academic discipline is taught either to graduate students (the most common model), or to undergraduate students (in a smaller number of educational institutions), or to undergraduate and graduate degrees (taking into account differences in the level of training and competences).

Within the framework of specialization and allocation of individual specializations, it was much easier to introduce new disciplines at senior courses, including medical law. The loss of specialization for bachelors' degrees has complicated the introduction of actual training courses in the educational process, even with the availability of the necessary teaching staff in the universities.

We believe that the variability in educational levels should be maintained, since in different institutions, with different directions of training lawyers, different tasks are being solved while forming their own, sometimes unique set of competencies. At the same time, the absence of the discipline "medical law" in the undergraduate programs, even as a choice discipline, the lack of students' awareness of the availability of such a direction in the legal personnel training leads to the lack of a coherent picture and deformations that negatively reflect on further legal practice, especially on the initial stage of the graduate's legal career.

Thus, the question of determining the sectoral affiliation of norms on public health protection causes considerable difficulties for interviewed students. Almost half of interviewed undergraduate students from Kutafin Moscow State Law University found it difficult to answer this question; a quarter included them in the subject of civil and (or) business law; fifteen percent – in the subject of social security law; three percent – in the subject of forensic medicine. Among the answers there were also: constitutional law, administrative law, etc.

It is noteworthy that the phrase "medical law" turned out to be familiar to more than seventy percent of the respondents. Most of them learned about its definition from the media, TV and radio programs, but not from the teaching staff and (or) additional educational literature recommended for the study.

Establishing the new educational practices

It should be noted that within the framework of the strategic development program of the Kutafin Moscow State University, significant work was done to establish the new academic discipline – the medical law of Russia. Methodical support of the new academic discipline for the bachelor's degree as well as the master's program "Master of Law in Healthcare (medical lawyer)" was prepared. Professors from a number of departments of the Kutafin University created and published a corresponding textbook [Mokhov, 2015].

Students took great interest in the discipline of "medical law". Currently, the management of the Kutafin University decided to expand the number of institutions where this subject can be taught.

A more complicated situation in Russia has developed with pharmaceutical law. So far we do not know the exact definition of "pharmaceutical law" or the approximate content of a possible academic discipline. It is possible to list only individual scientific, but not educational or educational-methodical works and publications on this topic [Melnikova, 2014; Mokhov, Olefir, 2017].

Students of law schools, as the study showed, do not know and have never heard from anyone about pharmaceutical law. Most of them found it difficult to even answer the question about what the pharmaceuticals and pharmaceutical market are. Only students of the Institute of Public Prosecutions of the Kutafin University, who during the period of training participated in joint audits conducted by the Prosecutor's Office and Roszdravnadzor (or Rospotrebnadzor) with pharmacy organizations, were able to affirmatively say that they are familiar with the pharmaceutical market.

At the same time, the market needs force us to quickly solve the emerging problems with the provision of legal personnel in this sphere of economic activity. To this end, at the first stage, it was decided to test the available developments in the preparation of masters' degree holders for a market economy, on the second stage, to prepare a fully-fledged training course for a new academic discipline. There are some of the main problems which can be noted: the unresolved basic theoretical and methodological problems of the course; the lack of special literature; the

lack of a sufficient number of qualified personnel with experience in this market and (or) scientific research in this field, teaching individual topics of the course. However, these problems are not specific, or especially unsolvable. The path of medical law development shows that, if there is a request of the relevant market with the support of the leadership from educational organizations and the legal community as a whole, the task of forming pharmaceutical law as an academic discipline in the coming years is completely solvable.

Литература

Блажеев В.В., Свистунов А.А. Проблемы и перспективы развития юридического образования // *Судья*. 2011. № 9. С. 17.

Малеина М.Н. Обоснование здравоохранительного права как комплексной отрасли законодательства и некоторые направления его совершенствования // *Медицинское право*. 2013. № 3. С. 7–14.

Мацкевич И.М., Власенко Н.А. Формализация специальностей научных исследований в сфере права: содержание и перспективы // *Журнал российского права*. 2013. № 6. С. 116–147.

Медицинское право России: учебник для бакалавров / отв. ред. А.А. Мохов. М.: Норма: ИНФРА-М, 2015. 336 с.

Мельникова О.А. Понятие фармацевтического права // *Медицинское право*. 2014. № 4. С. 21–24.

Мохов А.А. Преподавание медицинского права юристам – веление времени // Юридическое образование и наука. 2003. № 1. С. 32–34.

Правовые основы обращения лекарственных препаратов для медицинского применения: монография / отв. ред. А.А. Мохов, Ю.В. Олефир. М.: Проспект, 2017. 256 с.

Сергеев Ю.Д. Биомедицинское право России // *Медицинское право.* 2006. № 4. С. 3–4.

References:

Blazheev V. V., Svistunov A. A. Problems and prospects for the development of legal education. *Sud'ya*. 2011. № 9. P. 17. In Russian

Maleina M. N. Substantiation of health law as an integrated branch of legislation and some directions for its improvement. *Medicinskoe Pravo*. 2013. № 3. Pp. 7–14. In Russian

Matskevich I. M., Vlasenko N. A. Formalization of scientific research specialties in the field of law: content and prospects. *Zhurnal Rossiyskogo Prava*. - 2013. № 6. Pp. 116–147. In Russian

The Medical Law of Russia: a textbook for undergraduate programs/ Executive editor Mokhov A. A. M.: Norma: INFRA-M, 2015. P. 336. In Russian

Melnikova O. A. The concept of pharmaceutical law. *Medicinskoe Pravo*. 2014. № 4. Pp. 21–24. In Russian

Mokhov A. A. Teaching medical law to lawyers – the imperative of the time. *Yuridicheskoe Obrazovanie i Nauka*. 2003. № 1. Pp. 32–34. In Russian

The legal basis for the circulation of medicinal products for medical use: monograph / Executive editors Mokhov A. A., Olefir Y. V. M.: Prospekt, 2017. P. 256. In Russian

Sergeev Y. D. The bio-medical law of Russia. *Medicinskoe Pravo*. 2006. № 4. Pp. 3–4. In Russian

ЧТО ЧИТАТЬ



Акопов В.И. Медицинское право: учебник и практикум для вузов. М.: Юрайт, 2018. 287 с.

Главная цель настоящего учебника – помочь студентам вузов, обучающимся по медицинским направлениям и специальностям, а также учащимся средних образовательных организаций медицинского профиля, овладеть знаниями в области правового регулирования медицинской деятельности. В учебнике изложены теоретические основы медицинского права. Рассмотрены вопросы законодательного обеспечения охраны здоровья населения, права и обязанности медицинских организаций, медицинских работников, а также граждан в сфере здравоохранения, проблемы социальной и правовой защиты медицинских работников. Особое внимание уделено вопросам качества оказания медицинской помощи, видам его контроля и экспертизы, а также судебно-медицинской экспертизе. Проверить полученные теоретические знания студенты могут с помощью контрольных вопросов, тестовых заданий и ситуационных задач.



Медицинское право России: Учебник для бакалавров. Отв. ред. А. А. Мохов. М.: НОРМА: ИНФРА-М, 2017. 335 с.

Учебник подготовлен авторским коллективом ФГБОУ ВПО «Московский государственный юридический университет имени О. Е. Кутафина (МГЮА)» в соответствии с разработанной в Университете программой подготовки студентов юридических вузов России и на основе новейшего российского законодательства, правовой доктрины, правоприменительной практики. В нем отражена специфика правового регулирования медицинской деятельности, сферы здравоохранения, охраны здоровья граждан в Российской Федерации на современном этапе, рассмотрены основные правовые институты новой отрасли. Издание адресовано студентам юридических и медицинских вузов и факультетов, будет полезно организаторам здравоохранения, социальным работникам, всем интересующимся вопросами правового регулирования медицинской деятельности.