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The article is devoted to basic historical stages of establishment of the pharmaceutical faculty of the Yaroslavl State Medical University. Contribution of employees to the faculty development has been described. The work on training of the personnel for modern pharmaceutical industry has been shown. The structure of the pharmacy institute newly created on the basis of the faculty and its basic tasks have been provided. Outcomes of the activity of the faculty devoted to training of pharmaceutical personnel are summarized.

Keywords: faculty of Pharmacy, students, education, history

Author contribution: Lavrenteva LI — article concept, literature selection and analysis, data interpretation, writing a manuscript; Kulikova OA — literature analysis, data generalization, preparing a list of literature.

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ОПЫТ ПОДГОТОВКИ КАДРОВ НА БАЗЕ ФАРМАЦЕВТИЧЕСКОГО ФАКУЛЬТЕТА ЯРОСЛАВСКОГО ГОСУДАРСТВЕННОГО МЕДИЦИНСКОГО УНИВЕРСИТЕТА (ОТ ФАКУЛЬТЕТА ДО ИНСТИТУТА: ДОРОГА ДЛИНОЙ В 40 ЛЕТ)

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Статья посвящена основным историческим этапам становления фармацевтического факультета ЯГМУ. Представлен вклад сотрудников в развитие факультета. Показана работа по подготовке кадров для современной фармацевтической промышленности. Приведена структура вновь созданного на базе факультета института фармации, его основные задачи. Подведены итоги деятельности факультета по подготовке фармацевтических кадров.

Ключевые слова: фармацевтический факультет, студенты, образование, история

Вклад авторов: Л. И. Лаврентьева — концепция статьи, подбор и анализ литературы, интерпретация данных, написание рукописи; О. А. Куликова — анализ литературы, обобщение информации, оформление списка литературы.

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The faculty of pharmacy has begun its functioning in the Yaroslavl Medical Institute since September 1982. Tension associated with a shortage of pharmaceutical personnel in the Yaroslavl and adjacent regions provided the impetus for the faculty establishment. The faculty was created mainly owing to persistence of the head of the Yaroslavl State Medical Institute Prof. Novikov YuV and Chief of the Pharmacy Management of the Yaroslavl Regional Executive Committee Bredinin LE. Difficult early years were under supervision of Novikov Yu V. In the next 15 years, the faculty owes its development to the head of the Yaroslavl Regional Executive Committee Prof. Pavlov AV.

Prof. Titov NS, MD, was the first dean of the University. He was trying to solve many issues associated with opening of the faculty, including selection of personnel in profile disciplines. Subsequent establishment and development were done with participation of deans Prof. Laypanov AKh (1987–1995 г.) and Prof. Laypanova RYa (1995–2006). Lavrenteva LI, Pharm. D., who graduated from the Pharmacy Faculty, has been Dean of the Faculty since 2006.

Positive traditions in academic, scientific and social life of the faculty have been created by teachers from Kursk, Zaporozhe, Barnaul, and Ryazan. During the initial stage of the faculty development, a significant contribution was introduced by the first heads of newly created departments such as Prof. Laypanov AKh, Fursa NS, Laypanova RYa, Assistant Professor Vavilov VI. They were directly involved in development of new premises, purchase of equipment and selection of young personnel [1].

Initially, many students were admitted to the faculty (up to 150 people). At that time, employees of the faculty made every effort to improve training quality of personnel, formation and update of directions of scientific activity. During the years of establishment, heads and employees of pharmacy offices of the Yaroslavl, Kostroma, Vologda and other regions provided invaluable assistance to specialized departments. The largest and most innovative pharmacies became the bases for practical classes (head of pharmacy No. 90 Mayfetova AI, head of training and industrial pharmacy No. 160 Ledneva GA). Bases for practical training of students and performance of first theses were represented by other municipal and regional pharmacies and a regional control and analytical laboratory headed by Klikhnovskaya GE, and Yaroslavl Pharmaceutical Factory headed by Shishkin NA.

Skobykino educational and practical base was a base for practical classes in botany and pharmacognosy located on a picturesque bank of the Volga River on the territory of former

dachas of the Yaroslavl regional committees of the Communistic Party of the Soviet Union. It is equipped with a pharmacopeial and systematic site where over 500 plants grow until now.

Student's circles are functioning at all specialized departments since the moment of establishment. The most active and worthy participants perform and successfully defend diploma theses. Currently, the majority of teachers from specialized departments are represented by the faculty graduates and active participants of the student research society, whose diploma theses turned into doctoral researches.

The 1990s were not simple for our country. However, the faculty was developed during that period as well. At that time, the first dissertations were defended by the following faculty graduates: Grinenko NA, a student engaged in degree theses from the department of pharmacognosy (in 1992), and Slansky VE from the department of pharmaceutical and toxicological chemistry (in 1994).

The faculty has been international since 1992. Many foreign students (Syrian Arab Republic, Jordan, Kingdom of Morocco, Tunisia, Central African Republic, Republic of Kongo, etc.) have been educated there. The peak in numbers of students from this faculty occurs during this period. In 1997 the first graduation of masters of pharmacy, highly qualified specialists for foreign countries, took place.

The pharmaceutical market was developed due to the need in expansion of educational forms. Long-distance education has been initiated since 2002. There are numerous extension students (their number sometimes exceeded 100).

A great demand for professionals has led to a wide range of students by geography, age and profession [2]. The students included supervisors of pharmacy networks, teachers of colleges and universities, candidate of sciences. Acceptance on part-time study program was over since 2014 due to changes introduced into the Federal State Educational Standard.

However, the issue of deficiency of regional pharmaceutical personnel was still pressing. Considering these requirements, a new form of preparation of specialists with secondary pharmaceutical education (full-time and part-time) was opened in 2011.

In the beginning of the 2000s, pharmacies were the basic area of employment for our graduates. Those who work in this field should follow high professional and moral standards. Thus, from the first days of teaching, significant attention was paid to the issues of professional ethics and deontology and communication skills. The discipline called Basis of Professional Communication was included into the academic process. It was aimed at development of professional communication competence in the area of communication and interaction among the students. In future, it will allow them to perform a professional activity based on the most effective methods and forms of communication [3]. Knowing professional moral, ethical and communicative standards will contribute to constituent examination of specialized disciplines and proper organization of the process of pharmaceutical consultation.

Since 2014, the faculty has initiated the work on preparation of qualified personnel for pharmaceutical industry following adoption of Pharma-2020 state program heading for development and issuance of Russian innovation products [4]. By that time, a number of major projects related to construction of large pharmaceutical enterprises (Nycomed, R-Pharm, Pharmoslavl, Vitapharma, Teva, etc.) have been implemented in the region.

During this period, the faculty has been developing ties with pharmaceutical enterprises, which represented the bases for sightseeing, practices and probations for students. New disciplines such as GMP Rules, Pharmaceutical Logistics and Quality Control of Medicinal Preparations have been developed and implemented into the academic process [5]. As soon as factories have been constructed, the students had a unique possibility to study organization of modern pharmaceutical productions equipped in accordance with GMP requirements. Some practical classes were conducted at the Center of Technology Transfer of Ushinsky KD YSMU. It resulted in consolidation of theoretical knowledge.

Our students participated in the work of PHILIN pharmaceutical international camp, Pharmtech — Technologies of Pharmaceutical Industry exhibition, and — a bit later — at All-Russia GXP-summits and GXP-fests held with an international participation on the annual basis. The activities are aimed at the use of updated good practices in certain production situations and are career-oriented. It allows students to meet potential employees who can, in their turn, offer vacancies to the best students.

The project of All-Russia Pharmaceutical Academic Competitions is initiated under support of the Association of Russian Pharmaceutical Manufacturers. Our students are involved in all six organized academic competitions with successful demonstration of skills and knowledge; they occupy the first place of honor in one of them (Saint-Petersburg, 2015). All these activities became an essential part of preparation of our students to work in the pharmaceutical industry.

The pharmaceutical faculty of the YSMU has become member of the Chemical and Pharmaceutical Research and Educational Medical Cluster since 2017. It enables joint participation in development and implementation of educational and research programs and development of inter-university cooperation with other participants of the cluster.

Guidance counseling is an essential part of the faculty activity. Employees of the YSMU pharmaceutical faculty participated in the All-Russia forums conducted in Yaroslavl many times. Employees and students participated in the work of Health Territory site along with representatives of other educational institutions. R-Pharm was a traditional partner of the site. Schoolchildren learned about pharmacy-associated professions under the guidance of our teachers; they were absorbed in solving real production tasks offered by the faculty teachers.

The faculty employees have been actively involved in Path to Medicine program approved at the University. University Saturdays for schoolchildren of Yaroslavl and master classes are organized within the program. Moreover, excursions for schoolchildren at the University department are being conducted. The One Day at the University project when children can try themselves as students, go to different classes and make something with their own hands is being implemented. The activities do not only introduce schoolchildren to the profession, but also allow to try it. We have been cooperating with school No. 32 for the second year, where the Mendeleev class with in-depth study of chemistry and biology was organized. The Mendeleev camp, which could be attended during the autumn vacation, included visits to the University, meetings with teachers and future employers.

Students meet with potential employers on a regular basis. This year, the Day of Knowledge was organized for the first-year students, when they visited the largest pharmaceutical companies of Yaroslavl.

Approval of up-to-date perspective plans on development of the pharmaceutical branch until 2030 [6] made it necessary to modernize the faculty. In accordance with the order of Khokhlov AL, academician of the RAS and acting rector of the University, the faculty has been transformed into the Pharmacy Institute since September 1, 2022. The basic purpose of establishing and activity of the Institute consisted in compliance with the need of the pharmaceutical branch in highly-qualified specialists mastering

modern and advanced knowledge of the pharmaceutical science, undertaking research and investigation at a high level and implementation of the research results in the educational process. The structure of the institute includes the academic, scientific, organizational departments and Skobykino nursery of medicinal, aromatic and poisonous plants. The educational process is accomplished at 6 departments: department of pharmacology and clinical pharmacology (Prof. Khokhlov AL, Head of the Department and Academician of the RAS), department of management and economics of pharmacy (Assistant Professor Lavrentiev LI, Head of the Department), department of chemistry with a course of pharmaceutical and toxicological chemistry (Assistant Professor Kuznetsova ED, Head of the Department, Assistant Professor Smirnova AV, Head of the Course), and department of pharmacognosy and pharmaceutical technology (Assistant Professor Sidorov AV, Head of the Department).

Moreover, two basic departments were founded to intensify practical education such as the department of innovative pharmacy of the Yaroslavl branch of the Informational and Methodical Center for Examination, Accounting and Analysis of Treatment of Medical Means of the Federal Service for Surveillance in Healthcare and Department of Biotechnology and Industrial Pharmacy based on the Factory of Finished Dosage Forms of R-Pharm. Attraction of highly-qualified practitioners, bringing learning closer to real conditions of practical activity at these departments will promote preparation of specialists with competencies that correspond to modern requirements of the pharmaceutical branch.

The faculty provides preparation of highly qualified personnel (residents, postgraduates), implements programs of additional education (professional retraining, advanced training) in three fields of higher education (Management and Economics of Pharmacy, Pharmaceutical Technology, Pharmaceutical Chemistry and Pharmacognosy) and secondary education (Pharmacy). The primary and primary specialized accreditation for compliance with professional standards are provided [7,8,9,10]. Since 2016, the faculty has been actively involved in the system of continuous medical (pharmaceutical) education [11]. 15 programs of continuous education used by 3000 of students from different regions of our country have been developed during this period.

The institute is currently involved in preparation of specialists with higher and secondary pharmaceutical education. Activities on licensing of new master programs in Industrial Pharmacy and Biotechnologies are carried out.

In the future, the institute is aimed at subsequent development of material and technical resources, scientific and human resources; access of educational services, scientific development and medicinal preparations to the international level.

Our faculty has introduced a significant contribution to provision of the pharmaceutical branch with highly qualified specialists for 40 years. Over 3 thousand professionals have been prepared during this time. Many of them have become scientists, supervisors of large companies and contribute a lot to the development of the pharmaceutical branch of the country.

Opening and subsequent development of this faculty constituted response to requirements of time. Within the new organizational structure, the institute currently continues preparation of professionals who can solve modern tasks, act under changing social and economic conditions, and use new approaches to solving the tasks faced by the pharmaceutical branch.

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PROFESSIONAL ETHICS OF PHARMACEUTICAL PROFESSIONALS

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Professional activity in the sphere of pharmacological support means compliance with moral and ethical standards while fulfillment of labor functions by pharmaceutical professionals. The study purpose was to examine requirements for compliance with ethics and deontology placed on pharmaceutical professionals who carry out their professional activity. Study methods: content analysis, sociological survey, comparative analysis, mathematical and statistical methods, and ranking. Study materials: federal laws, orders of the Ministry of Health of the Russian Federation, occupational standards of pharmaceutical professionals, data from questionnaires of 95 pharmaceutical professionals. The performed analysis of regulatory documentation that regulates compliance with ethics and deontology by pharmaceutical professionals, examination of opinions of pharmaceutical professionals about the functions performed by them, identification of knowledge of those interviewed about constituents of ethics and deontology along with labor functions, fulfillment of which requires compliance with moral and ethical standards, displayed the necessity to improve knowledge and skills in the field of ethics and deontology at all educational levels.

Keywords: ethics, deontology, pharmaceutical professional, pharmacy, professional activity

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ПРОФЕССИОНАЛЬНАЯ ЭТИКА ФАРМАЦЕВТИЧЕСКИХ РАБОТНИКОВ

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Профессиональная деятельность в сфере лекарственного обеспечения предусматривает соблюдение фармацевтическими работниками морально-этических норм при выполнении трудовых функций. Цель исследования: изучить требования по соблюдению этики и деонтологии, предъявляемые к фармацевтическим работникам при осуществлении профессиональной деятельности. Методы исследования: контент-анализ, социологический опрос, сравнительный анализ, математико-статистические методы, ранжирование. Материалы исследования: федеральные законы, приказы Министерства здравоохранения РФ и профессиональные стандарты фармацевтических работников, данные анкет 95 фармацевтических работников. Проведенный анализ нормативно-правовой документации, регламентирующей соблюдение этики и деонтологии фармацевтическими работниками, а также изучение мнений фармацевтических работников о выполняемых ими функциях; выявление знаний респондентов о составляющих аспектах этики и деонтологии, а также трудовых функций, при выполнении которых фармацевтическим работникам необходимо соблюдать морально-этические нормы, показал необходимость повышения уровня знаний и умений в области этики и деонтологии на всех уровнях образования.

Ключевые слова: этика, деонтология, фармацевтический работник, аптечная организация, профессиональная деятельность

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To ensure effectiveness of pharmaceutical aid and proper professional activity, pharmaceutical professionals should follow ethical and deontological aspects [1]. Taking into account characteristics of professional activity in the sphere of pharmacological support, a pharmaceutical professional should have certain social and psychological personal traits that comply with requirements of the society, principles of pharmaceutical ethics and deontology [2]. The pharmaceutical community deals with the so-called pharmaceutical ethics that examines moral and ethical culture of a pharmaceutical professional, social significance of professional activity, requirements for the personality of a chemist (pharmacist), standards of behavior and ethical and psychological aspects of interrelations of all participants of pharmaceutical interaction [3].

It should be noted that pharmaceutical ethics is closely associated with pharmaceutical deontology, as they include general humane and common to humanity values, standards and rules of morality passing from generations to generations.

'Pharmaceutical deontology' currently includes the doctrine about the duty of pharmaceutical professionals, principles of behavior and attitude to their professional responsibilities aimed to provide specialists with knowledge necessary to carry out their functional duties that arise from the social value of the profession of a chemist (pharmacist) [3].

The category of debt has two levels: objective and subjective ones. The objective level is a set of responsibilities arising from a professional activity. The subjective level displays the attitude of pharmaceutical professionals to fulfillment of their responsibilities.

The interrelation between ethics of a chemist (pharmacist) and pharmaceutical deontology emerges from this unity [4].

Pharmaceutical ethics and deontology cover all types of professional activity of chemists and pharmacists, as

professional errors or crimes can inflict moral trauma on a person and social harm on the entire society; they also diminish the distinctive value of a pharmaceutical professional [5].

Thus, examination of issues of pharmaceutical ethics and deontology is considered pressing.

Study purpose: examine requirements for compliance with ethics and deontology placed on pharmaceutical professionals while performing a professional activity.

MATERIALS AND METHODS

The methods of content analysis, sociological interview, comparative analysis, mathematical and statistical methods, and ranging have been used during the study.

In accordance with the set purpose, content analysis of regulatory documents was done in the system of legal regulation of activity of pharmaceutical professionals and sociological study by questioning with Google-forms.

Federal laws, orders of the Ministry of Health of the Russian Federation and professional standards of pharmaceutical professionals were selected as research material for content analysis to detect requirements for compliance with ethics and deontology.

A questionnaire consisting of two sections was developed for the purpose of sociological research. The first section includes filter questions (gender, age, education, place of work, position, etc.) to reveal social and demographic characteristics of those interviewed. The second section embraces the basic issues grouped into four blocks that consider results of analysis of regulatory documents. The first block reflects opinions of pharmaceutical professionals about the performed functions, whereas the second and third ones are aimed to detect what those interviewed know about constituents of ethics and deontology; the fourth block consists of labor functions fulfillment of which must be accompanied by compliance with moral and ethical standards.

The study objects included 95 pharmaceutical professionals with 96.8% of them being women. The majority of those interviewed (39.7%) are elder than 50 years old, one-third part (34.7%) are younger than 40, and about one-fourth part (27.4%) are 40 to 50. 44.2% of those interviewed have higher education. 28.4% work as pharmacy heads, 21.1% as chemists and 48.4% as pharmacists. One responder (1.1%) is an individual entrepreneur with a license for a pharmaceutical activity. Those interviewed have a different length of service: over 15 years in 46.3%, 10 to 15 years in 14.7%, 5 to 10 years in 16.8% and not longer than 55 years in 22.1%. The majority of pharmaceutical professionals (64.2%) work at a pharmacy, one-third of them (30.5%) are employed at pharmacy branches, whereas 4.2% work at pharmacies of medical organizations. Almost two-third of them (63.2%) are employed by pharmacy networks.

The study method consisted of several stages. To analyze the survey results, those interviewed are subdivided into two groups: chemists and pharmacists. A percentage of those who selected separate options of responses is calculated during the first stage, the obtained results were ranked lately with a comparative analysis of groups being performed.

RESEARCH RESULTS AND DISCUSSION

The necessity to comply with ethics and deontology while performing a professional activity is recorded in a number of regulatory instruments of the Russian Federation.

In accordance with art. 73 of Federal Law No. 323 'On fundamental healthcare principles in the Russian Federation' as of November 21, 11 [6], pharmaceutical professionals conduct their activity in accordance with the legislation of the Russian Federation following the principles of medical ethics and deontology. Pharmaceutical professionals are responsible for compliance with medical confidentiality, including data about referral for medical aid, condition of health and diagnosis, and other data obtained during medical examination and treatment. Article 74 of the Federal Law [6] imposes restrictions on pharmaceutical professionals while performing a professional activity.

Compliance with professional ethics is one of the basic functions of pharmaceutical workers in accordance with the Rules of proper pharmacy practice regulated by Order of the Ministry of Health of the Russian Federation No. 647н as of August 31, 2016 [7]. The regulatory document also approves primary and subsequent preparation of workers regarding the issues of compliance with restrictions imposed on pharmaceutical workers while performing a professional activity in accordance with the schedule approved by the pharmacy supervisor [7].

Such professional standards as 'Pharmacist' [8], 'Chemist' [9] and 'Specialist Who Manages a Pharmaceutic Activity' [10] regulate a necessity to comply with professional ethics and deontology while performing a professional activity.

Analysis of requirements of professional standards to pharmaceutical professionals is provided in table 1.

The 'Pharmacist' standard [8] requires to comply with pharmaceutical ethics and deontology only while performing two general labor functions of a pharmacist out of three ones. Thus, while performing such a labor function as 'Retail trade and dispensing of medicinal products (MP)', it is necessary to perform professional communication with adherence to business etiquette and pharmaceutical deontology, whereas performing such a labor function as 'Wholesale of MP' requires compliance with ethical standards and knowing the rules of business communication, culture and professional ethics.

The 'Chemist' standard [9] demands knowing the basis of professional ethics and pharmaceutical deontology while performing all five labor functions of a chemist as the necessary ones. Other characteristics include adherence to moral and ethical standards within the professional activity while performing all labor functions of a chemist. According to 'Specialist Who Manages a Pharmaceutic Activity' standard [10], pharmaceutical ethics and deontology should be complied only when two out of six labor functions are performed. Explanatory work ensuring compliance with the principles of pharmaceutical deontology should be performed during 'Organization of work by the personnel of a pharmaceutical organization'. Performance of such a labor function as 'Organization of information and consultation aid for population and medical workers' requires knowing the basis of professional ethics and deontology only. Moreover, 'Other characteristics' section sets compliance with moral and ethical standards, principles of medical and pharmaceutical deontology within a professional activity while performing the labor function.

The performed analysis shows that the professional standards contain requirements to adherence to pharmaceutical ethics and deontology, though they are mentioned not in all labor functions and differ depending on the category of a pharmaceutical professional.

Analysis of knowledge of pharmaceutical professionals about basic functions performed while conducting a professional activity is presented in table 2.

It is seen from table 2 that those interviewed with higher and general education believe that compliance with professional

Table 1. Professional standards

Labor functions	Required skills/ knowledge/other characteristics	The content of requirements
The 'Pharmacist' professional standard		
Retail trade and dispensing of MP	Required skills	Perform professional communication with compliance of business etiquette and pharmaceutical deontology
	Required knowledge	–
Preparation of MP by pharmacies and veterinary pharmacy organizations	Required skills	–
	Required knowledge	–
Wholesale trade of MP	Required skills	Adherence to ethical standards
	Required knowledge	Rules of business communication, culture and professional ethics
The 'Chemist' professional standard		
Wholesale, retail trade and dispensing of MP and other pharmacy products	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards within professional activity
Acceptance control of incoming MP and other pharmacy products	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards within professional activity
Storage of MP and other pharmacy products	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards within professional activity
Informing population and medical workers about MP and other pharmacy products	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards within professional activity
Making MP at pharmacies	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards within professional activity
The 'Specialist Who Manages a Pharmaceutic Activity' standard		
Planning the activity of a pharmaceutical organization	Required skills	–
	Required knowledge	–
Ensuring resource provision of a pharmaceutical organization	Required skills	–
	Required knowledge	–
Organizing the work of the personnel of a pharmaceutical organization	Required skills	Perform professional communication on compliance with the principles of pharmaceutical deontology
	Required knowledge	–
Management of quality of results of the current activity of a pharmaceutical organization	Required skills	–
	Required knowledge	–
Management of information and consultation aid for population and medical workers	Required knowledge	Basis of professional ethics, pharmaceutical deontology
	Other characteristics	Compliance with moral and ethical standards and principles of medical and pharmaceutical deontology during a professional activity
Management of financial and economic activity of a pharmaceutical organization	Required skills	–
	Required knowledge	–

Table 2. Basic functions of pharmaceutical workers

Functions	Chemist		Rank	Pharmacist		Rank
	n = 42	Percentage,%		*n* = 53	Percentage,%	
Sale of pharmacy products of a proper quality	42	100.0	1	53	100/0	1
Provision of true information about pharmacy products, their cost, pharmaceutical counsellin	41	97.6	2–3	51	96.2	3
Informing about the rational use of MP for the purpose of responsible self-therapy	40	96.0	4	49	92.5	4
Making MP in accordance with recipes and inventories of MO	18	42.9	6	15	28,3	6
Registration of accounting records	36	85.7	5	43	81.1	5
Compliance with professional ethics	41	97.6	2–3	52	98.1	2

ethics occupies 2nd position amongst basic functions of pharmaceutical professionals.

Results of analysis of knowing the aspects of ethics by pharmaceutical professionals are presented in table 3.

Only 42.9% of chemists and 58.5% of pharmacists selected all constituent of ethics. Meanwhile, only 21.7% of pharmacy heads are well aware of ethical aspects. According to the majority of those interviewed, pharmaceutical ethics

Table 3. Constituents (aspects) of ethics

Ethical aspects	Chemist		Rank	Pharmacist		Rank
	n = 42	%		*n* = 53	%	
Moral and ethical culture of a pharmaceutical worker	40	95.2	2	51	96.2	1–2
Social significance of a professional activity	28	66.7	4	33	62.3	5
Requirements to the personality of a pharmaceutical worker	26	61.9	5	39	73.6	4
Rules of behavior of a pharmaceutical worker	42	100.0	1	51	96.2	1–2
Ethical and psychological aspects of interrelations of participants in the area of circulation of MP	37	88.1	3	48	90.6	3
Other	–	–	–	–	–	–

Table 4. Constituents (aspects) of deontology

Aspects of deontology	Chemist		Rank	Pharmacist		Rank
	n = 42	%		*n* = 53	%	
Relation to professional duties	30	71.4	2	42	79.3	2
Principles of behavior in a professional activity	39	92.9	1	48	90.6	1
The problem of debt while performing a professional activity	27	64.3	3	31	58.5	3

Table 5. Labor functions performance of which requires to observe the standards of ethics and deontology

Labor functions	Chemist		Rank	Pharmacist		Rank
	n = 42	%		*n* = 53	%	
Retail trade and dispensing of MP	39	92.9	1–2	47	88.7	1
Wholesale trade of MP	21	50.0	4	24	45.3	7
Making MP by pharmacies	16	38.1	8	18	34.0	8
Informing population and medical workers about MP and other pharmacy products	39	92.9	1–2	32	60.4	4
Acceptance testing of incoming MP and other pharmacy products	17	40.5	6–7	28	52.8	5–6
Storage of MP and other pharmacy products	17	40.5	6–7	28	52.8	5–6
Organizing the work of personnel of a pharmaceutical organization	34	81.0	3	40	75.5	2
Control of quality of results of the current activity of a pharmaceutical organization	19	45.2	5	34	64.2	3

primarily includes standards of behavior of a pharmaceutical professional.

Analysis of knowledge of deontology aspects by pharmaceutical professionals is presented in table 4.

According to the interview results, 47.6% of chemists and 47.2% of pharmacists know all aspects of deontology. Only 34.8% of pharmacy heads mentioned all constituents of pharmaceutical deontology. In accordance with the majority of those interviewed, the basic constituents included principles of behavior in the professional activity.

The results of analyzed opinions of pharmaceutical professionals by labor functions performed by them, fulfillment of which requires compliance with ethical and deontological standards, are presented in table 5.

In accordance with table 5, only 28.6% of chemists and 32.1% of pharmacists noted that it's necessary to comply with moral and ethical standards while performing all labor functions. Only 17.4% of interviewed pharmacy heads adhere to this point of view.

According to the majority of those interviewed, compliance with ethics and deontology are primarily expected while performing such a labor function as 'Retail trade and dispensing of MP'. Chemists also give the first place to 'Information of population and medical workers about MP and other pharmacy products', whereas it is only ranked 4th by pharmacists. Meanwhile, pharmacists stick to the opinion that it is necessary to comply with ethics and deontology while performing a labor function more than chemists. Besides, the interviewed pharmaceutical professionals mentioned the necessity of compliance with ethical and deontological principles while performing the labor function called 'Management of quality of results of the current activity of the pharmaceutical company' though this professional standard section lacks knowledge and skills in the field of ethics and deontology.

CONCLUSIONS

The study has shown that pharmaceutical professionals are not completely familiar with regulatory documentation. This is primarily reflected in limited comprehension of their basic functions. Pharmaceutical professionals are not well aware of basic aspects of ethics and deontology. They also underestimate the value of ethical and moral standards while conducting their labor responsibilities.

Supervisors of pharmaceutical organizations should ensure effective development of their personnel, which includes compliance with ethical and deontological principles required for professional activity.

Improved level of knowledge and skills associated with ethics and deontology should be given attention to during both the pre- and post-degree education. When future pharmaceutical professionals are being trained, the issues of ethics and deontology should be included into the programs of professional disciplines. As far as pharmaceutical specialists go, the ethical and deontological aspects should be included into advance training cycles and programs of continuous medical and pharmaceutical education.

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FORMATION OF PROFESSIONAL FLEXIBILITY AMONG PHARMACEUTICAL WORKERS TO INCREASE EFFECTIVENESS OF PROFESSIONAL INTERACTION

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The legislation of the Russian Federation in the area of regulation of a pharmaceutical activity has undergone changes aimed at provision of pharmacies with professionals having modern skills of effective professional interaction. Objective of the study was to examine the structure of professional flexibility and procedure of its formation. A sample consisting of 345 pharmaceutical workers including 283 chemists (82%) and 62 pharmacists (18%) was formed to implement the method of empirical research of professional flexibility. The method included diagnostic tools to examine the elements of professional flexibility. Pharmaceutical professionals who performed an effective professional interaction have a sufficient level of professional flexibility. The structure of professional flexibility was studied. It consists of cognitive, motivational value, socio-communicative, and reflective elements. The elements of professional flexibility were estimated using the diagnostic tools. The study results showed that it was necessary to form professional flexibility among pharmaceutical specialists. A set of academic disciplines embracing various levels of professional education was developed by us to reach the purpose. Depending on the level of professional education, the objective of disciplines and cycles was either to form the basis of professional flexibility, or shape its certain level.

Keywords: professional flexibility, professional interaction, pharmaceutical workers, cognitive element, motivational value element, socio-communicative element, reflective element, active learning methods

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ФОРМИРОВАНИЕ ПРОФЕССИОНАЛЬНОЙ ГИБКОСТИ ФАРМАЦЕВТИЧЕСКИХ РАБОТНИКОВ ДЛЯ ПОВЫШЕНИЯ ЭФФЕКТИВНОСТИ ПРОФЕССИОНАЛЬНОГО ВЗАИМОДЕЙСТВИЯ

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В законодательстве РФ в области регулирования фармацевтической деятельности произошли изменения, направленные на обеспечение аптечных организаций специалистами, владеющими современными навыками эффективного профессионального взаимодействия. Целью исследования явилось изучение структуры профессиональной гибкости и процедуры ее формирования. Для реализации методики эмпирического исследования профессиональной гибкости нами была сформирована выборка, состоящая из 345 фармацевтических работников, в том числе 283 провизора (82%) и 62 фармацевта (18%). Методика включала диагностический инструментарий исследования элементов профессиональной гибкости. Фармацевтические специалисты, осуществляющие эффективное профессиональное взаимодействие, обладают достаточным уровнем профессиональной гибкости. Нами была изучена структура профессиональной гибкости. Она состоит из когнитивного, мотивационно-ценностного, социально-коммуникативного и рефлексивного элементов. С использованием диагностического инструментария оценили элементы профессиональной гибкости. Результаты исследований указали на необходимость формирования профессиональной гибкости у фармацевтических специалистов. С этой целью нами разработан комплекс учебных дисциплин, охватывающий различные уровни профессионального образования. В зависимости от уровня профессионального образования задачей дисциплин и циклов было либо заложить основы профессиональной гибкости, либо сформировать ее определенный уровень.

Ключевые слова: профессиональная гибкость, профессиональное взаимодействие, фармацевтические работники, когнитивный элемент, мотивационно-ценностный элемент, социально-коммуникативный элемент, рефлексивный элемент, активные методы обучения

Вклад авторов: вклад всех авторов был равнозначным: анализ литературы, планирование исследования, сбор данных, анализ данных, интерпретация данных, подготовка черновика рукописи и др.

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The legislation of the Russian Federation in the area of regulation of a pharmaceutical activity has undergone changes aimed at provision of pharmacies with professionals having modern skills of an effective professional interaction.

Professional interaction (fig.) means a process of indirect or direct interpersonal interaction of healthcare specialists with patients. This process is influenced by environmental factors. It includes informational, organizational and psychological components. The process is supported by informational resources and rational assortment. Professional interaction is provided using information needs of professionals and patients in the ergonomic space of interaction.

Pharmaceutical professionals performing an effective professional interaction have a sufficient level of professional flexibility. Professional flexibility includes flexibility of behavior, resistance to social changes combined with self-actualization,

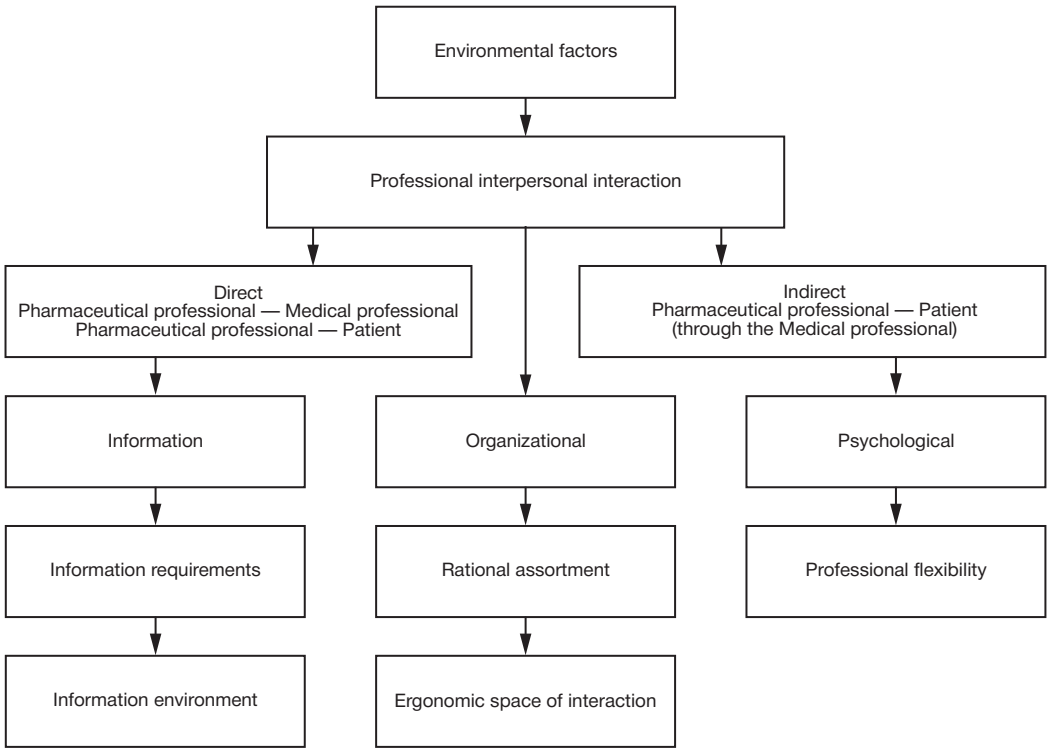

Fig. Model of professional interaction among pharmaceutical workers

Table. The structure of professional flexibility

Professional flexibility structure elements	Professional flexibility element description
Cognitive element	Professional knowledge, abilities and skills that form the basis of long-term relations with a consumer
Motivational value element	The value-and-meaning attitude toward a customer, self, profession, even temper; moral and ethical culture of a pharmaceutical worker; calmness; patience, self-control; self-restraint; flexibility of thinking, stress resistance
Socio-communicative element	Solving conflicts with a consumer, flexible behavior and communication strategies (communicability, type of response in case of a conflict), emotional burnout
Reflective element	Self-assessment, self-analysis of own activity, rethinking, updating a system of values

and ability to form long-term professional relations with a possible increase of the qualitative interaction level.

Professional flexibility can be considered as a 'soft skill' of pharmaceutical workers required for effective professional interaction under constantly modifying conditions of the professional environment [1–3].

MATERIALS AND METHODS

A sample consisting of 345 pharmaceutical workers including 283 chemists (82%) and 62 pharmacists (18%) was formed to implement the method of empirical research of professional flexibility. The method included diagnostic tools used to examine the elements of professional flexibility [4, 5].

The study objective included examination of the professional flexibility structure and procedure of its formation.

STUDY RESULTS

The structure of professional results has been examined by us (table).

A control test with 30 tests to evaluate expertise was used to determine the level of a professional flexibility cognitive element. Specialized questions in the test were about pharmacology, pharmacotherapy, getting prescriptions, using medicinal preparations in various age groups, etc. There was only one answer to every question. All correct answers were summed up; their percentage in the total number of possible correct answers was determined. A score was awarded based on the scale. A percentage of correct answers amounted to 81.3%. The value corresponded to 4 points ('satisfactory').

The motivational value element was analyzed using the questionnaire by Mehrabian A. As a result, 43% of those interviewed focused on avoiding failure. A specialist who avoids failures reduces its activity to making less errors preventing effective interaction with collegues and patients. 30% of pharmaceutical workers are focused on gaining success. These specialists use a creative approach to the activity, they are ready to set and solve new tasks. It should be noted that 27% of pharmaceutical specialists lack a dominant motivation at all.

Certain psychological personality traits (communicative competence, emotional intelligence, conflict response type, level of emotional burnout) were determined while analyzing socio-communicative elements. Mean values based on certain characteristics were obtained.

The reflective element was estimated using the method to diagnose the level of reflectivity by Karpov AV. The majority of those requested (52%) have a mean level of reflection. It means that pharmaceutical professionals can hardly evaluate their previous activities with subsequent extraction of professional

experience and it is difficult for them to form perspectives of their future behavior.

DISCUSSION OF RESULTS

The study results indicate that it is necessary to form professional flexibility among pharmaceutical specialists.

Formation of professional flexibility is a process when personality measures of a pharmaceutical worker are transformed improving his personal and professional activity. A set of academic disciplines embracing various levels of professional education has been developed by us to achieve the objective.

The results of conducted studies and requirements to professional standards were taken into account while developing working programs, additional professional development programmers and programs of an educational activity.

Learning theoretical material and practical skills was assessed using the initial, current and final control and the original fund of typical means of assessment (testing, solving situational tasks).

A program of joint educational activity named 'Prescription and dispense of medicinal preparations as an approach to professional interaction among healthcare specialists' was developed based on the study results to improve cooperation among medical and pharmaceutical workers.

The activity will be carried out within the system of continuous medical and pharmaceutical education.

Active methods of education such as discussion, gamification (put yourself in the position of the opponent), and facilitation (enables discussion in a group) are planned to be used during the activity.

Depending on the level of professional education, the objective of disciplines and cycles was either to form the basis of professional flexibility, or shape its certain level.

CONCLUSIONS

As a result of the study, a position of professional flexibility was determined in the structure of interaction among professional workers. Professional flexibility elements were diagnosed. An educational trajectory regarding formation of professional flexibility among pharmaceutical specialists was developed considering the results of conducted studies and requirements of professional standards.

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HUMANITARIAN APPROACH TO TEACHING AND STUDYING CHEMICAL DISCIPLINES

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Due to a high incidence of chemical compounds and chemical technologies, ethics of chemistry should apply in-depth knowledge aimed to reach the maximum of expected utility. This requires a certain concept of ethical and chemical orientation. The article describes certain elements of humanitarian approach used by us while studying chemical disciplines intended for 1st and 2nd year students in General Medicine, Pediatrics, Dentistry, Medical Biochemistry and Pharmacy.

Keywords: humanitarian approach, pedagogical technologies, problem-based learning, rating of educational achievements, objective and reliable control of educational achievements, personality-oriented approach

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ГУМАНИТАРНЫЙ ПОДХОД К ПРЕПОДАВАНИЮ И ИЗУЧЕНИЮ ХИМИЧЕСКИХ ДИСЦИПЛИН

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В связи с широким распространением химических соединений и химических технологий этика химии должна применять углубленные знания, направленные на максимум ожидаемой полезности, что требует определtнной концепции этико-химической направленности. В статье описаны некоторые элементы гуманитарного подхода, используемого нами при изучении химических дисциплин для студентов первого и второго курсов, обучающихся по специальностям «Лечебное дело», «Педиатрия», «Стоматология», «Медицинская биохимия» и «Фармация».

Ключевые слова: гуманитарный подход, педагогические технологии, проблемное обучение, рейтинг учебных достижений, объективный и надежный контроль учебных достижений, личностно-ориентированный подход

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The issues of quality and its assessment are particularly true for such areas of human activity as medicine and pharmacy. The level of competence, which is founded at a university today, will be presented to patients tomorrow. Among natural sciences, chemistry occupies a significant place in professional preparation of future physicians, pharmacists and chemists. It is perfect for formation of key competencies being an ideal testing ground for development of abilities to analyze data, think logically, make hypotheses and conclusions.

BODY OF THE TEXT

1st year students in General Medicine, Pediatrics, Dentistry, 1st — 5th year students in Pharmacy (in the higher education program,), 1st, 2nd, 4th and 5th year students in Medical Biochemistry, 1st and 2nd year students in Pharmacy (in the program of secondary vocational program) study at the department of chemistry with a course of pharmaceutical and toxicological chemistry of the Yaroslavl State Medical University. The following chemical disciplines are being taught: chemistry, general and inorganic chemistry, inorganic chemistry, physical chemistry, physical and colloidal chemistry, analytical chemistry, pharmaceutical chemistry, quality control of medicines, and toxicological chemistry.

Under conditions of mass education, the process of knowledge transfer and control of knowledge acquisition require that teachers should use the most up-to-date pedagogical technologies. The technologies allow to provide the minimum guaranteed knowledge and skills in accordance with the educational program and requirements of the Federal State Educational Standard. Individual characteristics of every student should be taken into consideration such as the basic level, rate of mastering the material, and cognitive abilities.

It is noted that the 1st year students can't work with literature, single out the most important things, and can't work independently. So, a humanitarian approach should be used during the academic process. Its elements are contained in the following forms of organization of the academic process at the department.

1. Another approach to a traditional form of education (lecturing). It consists in enlargement of didactic units, concentration on basic notions, terms, phenomena, generalization and analysis of notions. It is about the focus on those moments that can definitely be checked in any case, presentation not of the general, but of the basic information flow, which is subject to examination and verification. On the one hand, it significantly simplifies the process of adaptation of the 1st year students to learning at a university. On the other hand, teachers did useful work on structuring and selection of academic content, which is subject to control. The strategy is successfully implemented only when tests are actively used during certification. In lecturing content, a great attention is being paid to the history of most important discoveries in chemistry, biographies of known scientists, and illustration of interdisciplinary connections. To this end, visual multimedia aids are being actively used. Examination of life of scientists and their discoveries results in the establishment of connections between generations in Russian and world history of science. In this case, an instructional goal of the

educational process has been gained. Thus, the younger generation is provided not only with certain knowledge and skills, but also with moral values. As a result, an integrated personality is being formed. Ethics of chemistry is not possible without deepened knowledge [1].

2. Using the elements of problem-based learning, problem statement and finding solutions activate the mental activity of students and enhance cognitive interest. The set problems are solved during the joint activity of a teacher and a student.
3. Monitoring of academic achievements of students with regular tracing and publication of the current rating as elements hereof. This is a motivating factor for all students. Weak students are trying to improve their positions, whereas strong students are attempting not to lose what has been achieved. A competitive element in academic achievements has been utilized. Moreover, students from the bottom of the list are urged to visit consultations, use departmental texts and collections of tests developed at the department. It has long been noted that the rating system allows to activate the cognitive activity, stimulates daily independent work and increases interest in the subject [2, 3].
4. Stable rules assessing academic achievements and assessment predictability. Students can get familiar with requirements to the lower and upper ranges of estimates of their academic achievements in accordance with the Discipline Rating Regulation during the first lesson.
5. Open requirements to the minimal scope of content of controlled data formulated as an open bank of tests, which can be used for self-preparation and self-checking. Thus, the humanitarian principle of warranted educational minimum (active cooperation in self-preparation and self-checking) has been implemented. Formation of the bank of tests is preceded by a hard work of the most experienced teachers who carefully select the content of controlled material. The 'nucleus' of the academic discipline, key notions and regularities take the form of tests. Scientifically valid tests, a part of which has a reliability coefficient of 0.90, have been developed at the department. Those who pass the tests get a just and objective mark. Paper-based tests are unified by content and moderate difficulty.
6. Writing a paper on one of the issues for obligatory independent studying by choice or on the topic suggested by a teacher promotes development of the skills of independent work.
7. Combination of criterion-oriented and regulation-oriented approach to assessment of academic achievements of students. The objective of the regulation-oriented approach is to differentiate students by their achievements, finding the strongest ones who can be exempted from an exam, and giving aid to the weakest. The approach forms the basis of the rating system. The purpose of criterion-oriented approach is to check the educational minimum. In this case, criterion-based tests (incoming control, control of knowledge survival and exam) are used [4].
8. Interim step-by-step certification on the discipline. The stages include as follows: a) estimation of practical skills, b) assessing the skill to solve standard tasks, c) assessing knowledge of theory basis according to the results of an examination testing considering the final rating. To solve the tasks, the student needs to be aware of certain data, have solving skills, quick thinking, general intelligence, be able to perform important tasks, correctness of which is checked with participation of a teacher. Problem solving is not specifically taught, no ready-made solutions are available in books. The probability of providing a correct decision is a function of human mental abilities (ability to process information) and poorly depends on whether the test was passed successfully (correctness of answers to tests) [5]. The educational minimum is tested for compliance with educational standards when every tested subject can try to do all tests at least once (unlimited testing). Setting up a time limit for the test brings (thinking) abilities of students to the forefront.

   As compared with a traditional exam, three-stage certification is characterized by less emotional stress, and more objective and reliable assessment. The selected form is organically combined with the form of final certification of graduates of the pharmaceutical faculty.

CONCLUSION

Summarizing the above, it should be noted that the humanistic orientation is an important aspect of the entire preparation process of specialists. However, chemical sciences occupy a special place in this case. They are fundamental and have certain logic of construction and solid interdisciplinary connections. They help to provide a student with an integral idea of chemistry of life on their basis.

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TEACHING CLINICAL PHARMACOLOGY AT THE PHARMACEUTICAL DEPARTMENT OF THE YAROSLAVL STATE MEDICAL UNIVERSITY

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The main objectives that arise while teaching future chemists currently include formation of knowledge, abilities and skills of pharmacological support of treatment of diseases that enable effective work aimed at implementation of professional tasks and degree of mastery over labor functions. While teaching clinical pharmacology at the pharmaceutical department, we follow the path of an increased scope of new topics on private matters of the discipline including assessment of effectiveness and safety of medicinal preparations taking into account adverse reactions, issues of pharmacoeconomics, pharmacoepidemiology and provisions of evidence-based medicine. In Russian medicine, it is common to adhere to the principle that moral standards are interwoven into clinical practice. This principle is followed during teaching. Proper management of the educational process will enable students to independently work with literature, critically assess new data and continuously improve their professionalism in future.

Key words: clinical pharmacology, teaching, evidence-based medicine

Author contribution: Speshilova SA — study planning, data collection, data analysis, data interpretation, preparation of a draft manuscript, article concept, literature selection and analysis, synthesis of information, writing a text; Sinitsina OA — study planning, data collection, data analysis; Lileeva EG — article concept, literature selection and analysis; Demarina SM — preparing a list of literature; Palyutin ShH — literature selection and analysis, data synthesis, writing a text.

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ПРЕПОДАВАНИЕ КЛИНИЧЕСКОЙ ФАРМАКОЛОГИИ НА ФАРМАЦЕВТИЧЕСКОМ ФАКУЛЬТЕТЕ ЯРОСЛАВСКОГО ГОСУДАРСТВЕННОГО МЕДИЦИНСКОГО УНИВЕРСИТЕТА

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Основные задачи при обучении будущих провизоров в настоящее время — это формирование знаний, умений и навыков фармакологического обеспечения лечения заболеваний, позволяющих осуществлять эффективную работу по реализации задач профессиональной деятельности, и степень овладения трудовыми функциями. Развитие преподавания клинической фармакологии на фармацевтическом факультете идет по пути увеличения объема новых тем по частным вопросам дисциплины, в том числе по оценке эффективности и безопасности лекарств с учетом проявлений нежелательных реакций, а также вопросов фармакоэкономики, фармакоэпидемиологии и положений доказательной медицины. В процессе преподавания дисциплины сохраняется традиционная для российской медицины позиция, что моральные нормы вплетены в клиническую практику. Грамотная организация учебного процесса позволит студентам в дальнейшей их деятельности самостоятельно работать с литературой, уметь критически оценивать новую информацию и непрерывно повышать профессионализм.

Ключевые слова: клиническая фармакология, преподавание, доказательная медицина

Вклад авторов: С. А. Спешилова — планирование исследования, сбор данных, анализ данных, интерпретация данных, подготовка черновика рукописи, концепция статьи, подбор и анализ литературы, обобщение информации, написание текста; О. А. Синицина — планирование исследования, сбор данных, анализ данных; Е. Г. Лилеева — концепция статьи, подбор и анализ литературы; С. М. Демарина — оформление списка литературы; Ш. Х. Палютин — подбор и анализ литературы, обобщение информации, написание текста.

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The history of department of clinical pharmacology (CP) is associated with creating a course of clinical pharmacology at the department of faculty therapy of the Yaroslavl Medical Institution in 1984 and beginning of teaching at the therapeutic faculty, and at the pharmaceutical faculty as part of pharmacotherapy since 1986. The increasing need in better knowledge of CP among chemists was the reason for occurrence of this discipline at the department in 2005. However, students of the pharmaceutical faculty faced the problem of assimilation of a large amount of knowledge; for this, knowledge of many other disciplines had to be synthesized. Elective course named 'Basis of internal diseases. Pharmacoeconomics' played a remarkable practical role in 2014. It promoted better integration of students into the subsequent educational process at this department. Subsequently, teaching CP at the pharmaceutical department was accompanied by an increased number of new topics on private issues of the discipline including assessment of effectiveness and safety of drugs considering adverse reactions and issues of pharmacoeconomics, pharamcoepidemiology and provisions of evidence-based medicine [1, 2].

Modern economy of the XXI century requires a presence of highly qualified employees on the labor market. They should have professional competencies. Thus, high requirements were placed on them including chemists [3, 4]. In the presence of a large arsenal of medicinal products (MP), a professional should do as follows:

1) analyze the rationality of selection based on criteria of effectiveness and safety of a certain MP in the group of analogous products to treat the basic symptom complexes;

2) conduct a pharmaceutical consultation of patients on correct regimen of MP intake, especially regarding novel dosage forms or their combinations;
3) provide recommendations on prevention of adverse drug reactions;
4) inform physicians of pharmacodynamics, peculiarities of pharmacokinetics, interactions of newly arriving MP, offer a rational alternative to the old MP and those lacking at the time of referral.

A pharmaceutical professional interacting with medical personnel, patients and their relatives, regulatory and oversight bodies should also comply with the rules of medical and pharmaceutical ethics and deontology. A chemist has a moral responsibility for possible negative consequences when MP are created, during clinical trials, manufacture and implementation, quality control of pharmaceutical products and advertising [2, 4].

Presence of a large number of reproduced MP among the registered preparations with unproved effectiveness and safety, a significant difference in the cost of MP with the same international nonproprietary name, excess of doubtful information, and false advertising complicate the chemist's activity. Many issues can be solved using clinical pharmacology [5, 6].

At the Yaroslavl State Medical University, CP is taught to the chemists in accordance with the program composed as per requirements of the Federal State Educational Standard of Higher Education in the specialty of Pharmacy (33.05.01) [2].

CP is taught in the 4th and 5th years, whereas during the 3rd year the students are trained in the abovementioned elective discipline. The current basic tasks achieved during education of future chemists include formation of knowledge, abilities and skills of pharmacological support of treatment of diseases that enable effective work associated with implementation of professional tasks and degree of mastery in labor functions. Highly qualitative medical education can be provided only due to a rational combination of traditional methods of preparation with innovative classic classroom sessions with a wide use of remote technologies, enough time for independent and practical work under the guidance of an experienced mentor [7, 8]. Independent work of pharmaceutical students on rational prescription of drug therapy and drafting a formulary is the basis of practice-oriented training provided at the department. It visually confirms mastering the necessary competencies [9, 10].

Solving clinical issues makes students closer to their future practical activity, promotes deep understanding of the need for theoretical knowledge of CP and makes new data handling possible. This type of education requires attraction of knowledge related to various subjects and enables formation of interdisciplinary connections. This is necessary to master general professional competence [7, 11].

Progressively increased scope of CP-related data assigns serious tasks regarding perfection of the pedagogical process to the teacher as well. The teacher and student nature of interaction has changed when the lessons were organized, and the interactivity became the main method, especially during an attempt to find the best solution by analyzing errors and reviewing actual practical cases. Thus, it is important that a teacher should necessarily be a physician and could show his critical thinking in a proper way [12, 13]. It always attracts great interest among students and evokes an emotional response making the educational process more effective and turning complex issues into more understandable ones.

Moreover, a teacher should make the students interested in the subject, form motivation and stimulate creative thinking using properly asked questions. It is necessary be always patient about the students' mistakes they make while trying to reach at a conclusion, offer aid or use required sources of information when the student is not able to find answers independently. Acquisition of certain experience in the process of education is important. Thus, directive rules on practical lessons should be avoided with simultaneous direction of students to the right path [7–9, 14].

In modern education, using tests is a rational and effective addition to other methods of knowledge control. It is widely applied at our department along with online testing. Practical testing enables detection of the level of knowledge, abilities and skills among pharmaceutical students. Tests and joint review of results motivate the students to activate the work on mastering the educational material [7, 14]. Moreover, testing disciplines, organizes and shapes the activity of students.

Oral interrogation is traditionally used at the department as well. It enables to find a correct answer, its consequence, independence of judgements and conclusions, degree of development of logical thinking in a future chemist. This form is used to perform current control of the level of knowledge. It basically concentrates on identification of problem areas in learning, complex issues, phenomena and situations. Collective work of the entire group is definitely used during interrogation as addressing a question to everyone, reviewing the answer and assessing answers of the student or his/her colleagues.

The role of students' cognitive activity, their motivation to independent academic work including the one in electronic educational environment sharply increases [10, 15]. The advantage of the practical approach is that it is organically combined with various modern educational technologies being their integral part.

Unlike many fundamental academic disciplines, clinical pharmacology can't be learned once and for all. Teachers have to get ready for lectures, practical classes on a constant basis updating and analyzing new data [5, 6, 8].

Overall, a chemist should know not just medical and pharmacological disciplines, but also economic and marketing fundamentals, meaning that they should be executed in a qualitative way in accordance with the ethical standards. Today, the Ethical Code of a Russian Pharmacist is in force in Russia [4, 12, 16]. It is based on the Federal Law 'On the Fundamental Healthcare Principles in the Russian Federation', consumer and patient protection legislation, legislation on advertising, Civil Code of the Russian Federation and other legislative acts of Russia, documents of the UN, WHO and other documents related to ethical aspects of pharmaceutical business [2–4]. Employees of the department pay a great attention to the issues of ethics as well. The worldview of students has been shaped during the entire educational period with subsequent improvement of professional skills throughout life. Thus, formation of ethical and deontological culture of future specialists at medical universities is of an exceptional value [15, 16]. A traditional approach stating that ethical standards are build in the clinical practice has been preserved in the process of the discipline teaching.

CONCLUSION

Formation of the personality of a future chemist at a higher school is a complicated and multi-faceted process success of which is mainly ensured by organization and planning the activity of students, active fulfillment of the educational standard for this specialty, creation of external and internal conditions for intensive development of necessary professional attributes [1, 2, 3]. Proper organization of the educational process will allow students to independently work with literature, being able to assess new information in a critical way and continuously improve their professionalism.

Teaching any academic discipline must result in a qualitative preparation of a graduate by solving the issues while getting education at the university.

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THE VALUE OF THE STATE SEGMENT OF THE REGIONAL PHARMACEUTICAL MARKET IN THE SYSTEM OF DRUG SUPPLY CONSIDERING PERSPECTIVES AND RISKS OF DEVELOPMENT

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No properly formed and subsequent regulation concept has been presented until now by a number of the issues, which are essential for the pharmaceutical branch. Development and a complex structure of the state regional retail market of medicines, including the activity objects as part of organizations with various organizational and legal forms managed or coordinated by representatives of public entities, have been reviewed in complex within the trial. The model of the structure of the state segment considering organizational and legal interactions used during examination of the regional pharmaceutical market in the Kostroma region has been suggested. Distribution of objects within the state segment structure was analyzed. The differences in the strategies of functioning and development of the state and private segments of the regional retail market of medicines have been identified. Legal preconditions and social and economic conditions of the growing role of healthcare institutions in the system of drug supply of population have been designated. It has been established that the tendencies intensifying participation of the state in the system of drug supply to ensure proper management of budgetary resources and risk prevention were accompanied by previously adopted extra-branch changes of legislation. This could result in reduction of the state segment in economics that would inevitably lead to serious changes in the structure of the pharmaceutical market and redistribution of social load among its participants [2]. A serious understanding of prospects of functioning of the state segment of retail trade of medicines is required both at the level of regulatory agencies and within the professional community considering the preservation of social services of medicinal aid and decreased risks of negative phenomena on the pharmaceutical market.

Keywords: state segment, prospects and risks for the development of the pharmaceutical market, regional drug retail market, drug supply system, drug care social services

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ЗНАЧЕНИЕ ГОСУДАРСТВЕННОГО СЕГМЕНТА РЕГИОНАЛЬНОГО ФАРМАЦЕВТИЧЕСКОГО РЫНКА В СИСТЕМЕ ЛЕКАРСТВЕННОГО ОБЕСПЕЧЕНИЯ С УЧЕТОМ ПЕРСПЕКТИВ И РИСКОВ РАЗВИТИЯ

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По ряду принципиальных для фармацевтической отрасли вопросов до настоящего времени не представлено четко оформленной, последовательной концепции регулирования. В рамках настоящего исследования всесторонне рассмотрены развитие и сложносоставная структура государственного сегмента регионального рынка розничной торговли лекарственными препаратами, включающего объекты деятельности в составе организаций различных организационно-правовых форм, находящихся под управлением либо координацией представителей публичных образований. Предложена модель структуры государственного сегмента с учетом организационно-правовых взаимосвязей, использованная в изучении регионального фармацевтического рынка на примере Костромской области. Проведен анализ распределения объектов структур государственного сегмента, выявлены различия стратегий функционирования и развития между государственным и частным сегментами регионального рынка розничной торговли лекарственными препаратами. Обозначены правовые предпосылки и социально-экономические условия возрастающей роли учреждений здравоохранения в системе лекарственного обеспечения населения. Установлено, что наряду с тенденциями усиления участия государства в системе лекарственного обеспечения в целях рационального распоряжения бюджетными ресурсами и предотвращения рисков, вступили в силу ранее принятые внеотраслевые изменения законодательства, последствием которых должно стать сокращение в экономике государственного сегмента. Это неминуемо повлечет серьезные изменения в структуре фармацевтического рынка и перераспределение социальной нагрузки между его участниками. На уровне органов государственного регулирования и в профессиональном сообществе требуется серьезное осмысление перспектив функционирования государственного сегмента рынка розничной торговли с позиций сохранения социальных услуг лекарственной помощи, снижения рисков негативных явлений на фармацевтическом рынке.

Ключевые слова: государственный сегмент, перспективы и риски развития фармацевтического рынка, региональный рынок розничной торговли лекарственными препаратами, система лекарственного обеспечения, социальные услуги лекарственной помощи

Вклад авторов: вклад всех авторов был равнозначным: анализ литературы, планирование исследования, сбор данных, анализ данных, интерпретация данных, подготовка черновика рукописи.

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No properly formed and subsequent regulation concept has been presented until now by a number of the issues, which are essential for the pharmaceutical branch. This concerns the position on the pharmaceutical market and participation of state structures in the circulation of medicinal preparations (MP). In the growth of consolidation on the pharmaceutical market, which results in merging of business players, increased concentration and change in the competitional environment, an increase of qualitative attributes of the pharmaceutical market doesn't warrant growing affordability of drug supply because it has a territorial irregularity, can be accompanied with negative phenomena both in relation to population servicing indicators and profitability of pharmacy business.

Importance of comprehension and distinct, subsequent legalization of the state position on these issues is of principal value as it directly influences how affordability of medicines, one of the most important warranties in the field of health protection, is being implemented.

It is pressing to examine the condition and affordability of drug supply from the perspective of public interests in the sphere of development of regional pharmaceutical markets, affordability of pharmaceutical services for the population from different territories depending on its density, retail infrastructure, and detection of key segments in distribution of social load between participants of the pharmaceutical market.

The purpose of this study was to analyze the structure and condition of the state segment of the regional drug retail market considering assessment of its value in the system of drug supply, prospects and risks for the development established considering the problems of acting and suggested legal regulation.

Methods represent content analysis of regulatory instruments in the field of pharmaceutical activity, regulation of competitive markets, methods of a retrospective and statistical analysis, modeling, comparative and predictive analysis.

RESULTS

Structure and legal conditions of the presence of the state segment on the drug retail market

Legal and institutional structure of the state segment on the regional drug retail market for over than 20 years underwent changes towards complication. It is not homogenous today.

Impossibility to ensure provision of certain social services using the market instruments only resulted in active development of state and municipal unitary pharmaceutical enterprises with the liability established by the legislation as far as decision of these tasks by the state bodies of the entities of the Russian Federation and local authorities goes. The legal basis was established by Federal Law as of November 14, 2002 No. 161-FZ 'Concerning state and municipal unitary enterprises'. According to it, creation and functioning of enterprises with a respective organizational and legal form were provided if 'it is necessary to perform an activity to solve social tasks (including implementation of certain goods and services at a minimum cost) …'.

However, the measures were not sufficient and totally effective. The mechanisms that ensure control over compliance of the activity of unitary enterprises with the purposes of their establishment set by the law were not legally determined [1]. Under real economic conditions, the most important task of drug supply affordability for rural population was not solved along with performance of social pharmaceutical services (preferential provision of medicines, discharge of narcotic agents and psychotropic substances, drug preparation).

As a response to the social request established by Federal Law 'Concerning Circulation of Medicines', provisions on retail trade of medicines by medical organizations and their rural subdivisions have been introduced considering the following peculiarities:

1) Pharmaceutical activity is performed by medical organizations and their subdivisions in accordance with a close list of their subdivisions (outpatient departments, feldsher stations (FS) and feldsher-midwife stations (FMS), departments of general medical and family practice).

In accordance with the terms accepted by Federal Law No. 61-FZ, the subjects (objects) of retail trade of medicines are not pharmacies.

Thus, rules of binding nature which relate to the provision of pharmaceutical services are associated not with pharmacies, but with medical companies with initially different tasks of the basic statutory activity. To develop the standard, order of the Ministry of Health and Social Development of Russia as of May 15, 2012 No. 543н 'Concerning Approval of the Provision on Organization of Primary Medical and Sanitary Aid to Adults' states that the basic tasks of FMS include 'implementation of medicines and medical devices in the lack of pharmacies on the settlement territory' (*par. 11 of Exhibit No. 15 to Provision on Organization of Primary Medical and Sanitary Aid to Adults, approved by Order of the Ministry of Health and Social Development of Russia as of May 15, 2012 No, 543н*).

2) Retail trade of medicines by a medical subdivision is implemented using the territorial location in a village in case of obligatory presence of such a qualifying attribute as a lack of pharmacies in the village.

Thus, the legal field determines how to solve the social and economic issue using not the market (competitive), but administration and organization method as the only possible one under the prevailing conditions. Moreover, it is obligatory to exclude this scheme from the competitive environment.

Thus, the task can be solved beyond industry not by way of intersectoral cooperation but through a transfer of functionality of subjects of retail trade of medicines to institutions of public healthcare with a complete set of civil and administrative legal relations, including the ones of a delicate nature, in the event of liability.

3) Management and organizational decisions to implement the socially significant service are taken by the management healthcare body of the entity of Russia (part 5 article 55 of Federal Law No. 61-Z) and supervisors of a medical organization.

Meanwhile, it should be noted that neither currently invalid order of the *Ministry of Health and Social Development* of Russia as of August 26, 2010 No. 735н, nor accepted later Rules of Good Pharmacy Practice reflect peculiarities of business processes of organization and functioning of this form of drug retail. Principally different working schemes were practically developed in many regions considering understanding of economic feasibility in the lack of a distinct legal regulation of retail processes in rural medical subdivisions. It was done independently and using organizational means.

The accepted complex of legal and organizational measures resulted in significant qualitative and quantitative changes in the regional and local markets of medicines and increase of a state segment share in their structure. The tendency is not only preserved, but has also been growing stronger.

Meanwhile, various and frequently multidirectional processes occur as far as the functioning of the state segment of the pharmacy sector goes.

The state segment structures on the pharmaceutical market are developed and intensified in a number of regions. At the same time, a tendency of conversion of unitary enterprises into more commercially free structures such as business companies with preservation of the public owner, and establishment by unitary enterprises of business entities as branch organizations with a single management system has been lately observed.

The processes were activated in 2018 following entry into force of changes introduced by Federal Law as of December 31, 2017 No. 505-FZ 'Concerning introduction of changes into certain legislative acts of the Russian Federation' into Federal Law as of July 18, 2011 No. 223-FZ 'Concerning purchase of goods, works and services by separate types of legal entities. In accordance with them, a list of legal entities was expanded including unitary enterprises subject to requirements to organize purchases.

On the contrary, unitary enterprises in some regions were transformed into non-commercial companies such as state and municipal institutions (budgetary institutions and autonomous companies) with preservation of profile functions of wholesale and/or retail trade of drugs:

Thus, the structure of the state segment on the drug retail market was complicated slowly in relation to the subjects involved and a variety of business structures. It was all due to the following tasks:

- warranted provision of social services of drug supply by unitary enterprises and subsequently by companies of other legal organizational forms,
- ensuring competitiveness of the functioning companies within the growing competition and more stringent requirements to performance of financial and economic activities by way of transfer of unitary enterprises and establishment of commercial companies such as business entities;
- to prevent risks of losing control while liquidation of unitary enterprises/privatization of commercial entities, preservation of the resource by public and local authorities by way of transfer of the mentioned economic entities into other, non-commercial companies such as budgetary and autonomous organizations.

In a broad sense, the state segment in the drug retail market is represented by economic entities, establishing and/or coordinating the activity of which are done in direct or indirect involvement of a participant (authorized bodies) of public entities such as constituents of the Russian Federation and municipal formations. This is how the presence of the state segment on the local markets within separate municipal entities and on the entire regional pharmaceutical market has been formed.

In accordance with the narrow legal corporate classification, the state and municipal organizations relate to different forms of property. However, analysis of logics and meaning during the study allows to include these structures into the single state segment on the drug retail market considering their principles and activities.

In the legal aspect, elements of the following types shape the state segment of the regional retail market of medicines at the present stage:

1) pharmacy organizations of state (municipal) unitary enterprises;
2) pharmacy organizations of business entities with a representative of the public owner being included into the composition of the founders;
3) pharmacy organizations of subsidiary economic companies with state (municipal) unitary enterprises being their founder;
4) pharmacy organizations represent separate (structural) units of state (municipal) institutions such as medical organizations;
5) pharmacy organizations represent separate (structural) units of state (municipal) institutions not represented by medical organizations;
6) state (municipal) institutions represented by medical organizations and their subdivisions (feldsher stations (FS), feldsher-midwife stations (FMS), outpatient clinic (OC), GPs) that exercise retail trade of medicines in rural areas with no pharmacy organizations.

The schematic image of the legal structure of the state segment of the regional drug retail market at the present stage is presented in figure 1.

The used model of the legal structure of the state segment of the regional drug retail market was applied to a certain regional pharmaceutical retail market of medicines in the Kostroma region. Organization of the state segment occupies a valid position in its functioning (fig. 2). In the region, this segment consists of 28 entities, which perform retail trade of medicines within 423 sites including 76 pharmacies and 347 separate medical subdivisions. Legal and organizational forms of the entities that sale medicines, organizational and structural interactions are presented in the figure.

Apart from the subjective composition of the state segment of regional and local retail markets of medicines, it is also necessary to consider quantitative attributes of regional pharmaceutical market participants and their role in provision of socially significant services of giving medicinal aid to population.

Quantitative attributes of the state segment of retail trade of medicines, role in establishing the infrastructure of dispensing medicines and providing socially significant services of medicinal aid

The performed analysis of distribution of objects (implementation sites) in the structure of the state segment of retail market of medicines within the region by the example of the Kostroma pharmaceutical market (fig. 3) clearly shows the correlation in the structure of the state segment of pharmacy organizations (PO) and subdivisions of healthcare institutions.

In accordance with the presented analysis, 84% of places of medicine supply in the market state segment structure of the Kostroma region are represented by healthcare institutions mainly through separate subdivisions of OC, FMS, FS and, to some extent, by establishing pharmacy organizations. 18% can be attributed to pharmacy organizations of unitary enterprises and enterprises of other organizational and legal forms of a state (municipal) origin.

A change in the qualitative composition of the state segment on the drug retail market altered the market infrastructure, promoted a considerable quantitative growth of objects of retail trade of medicines and increased warranted affordability of medicinal aid provided to population owing to healthcare institutions.

Having considered the composition, structural features and tasks of activity of state organizations on the pharmaceutical market, it is necessary to estimate the position and value of the state segment in relation to other participants of the entire regional market.

Analysis of the pharmaceutical market in the Kostroma region regarding detection of the state segment share is presented in table 'Distribution of retail trade objects of medicines in the structure of the pharmaceutical market in the Kostroma region regarding detection of the state segment share (table). State pharmacy organizations and separate

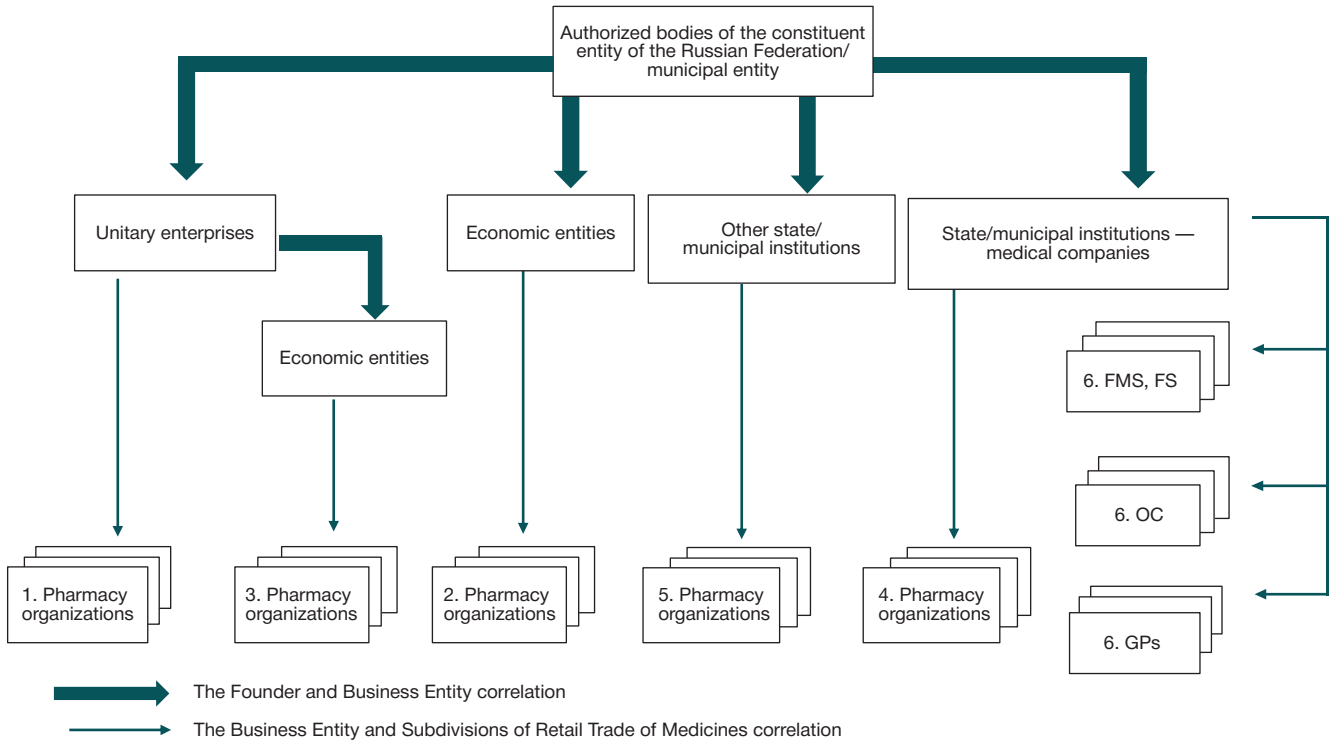

Fig. 1. Legal and organizational structure of the state segment of retail drug market in the Kostroma region

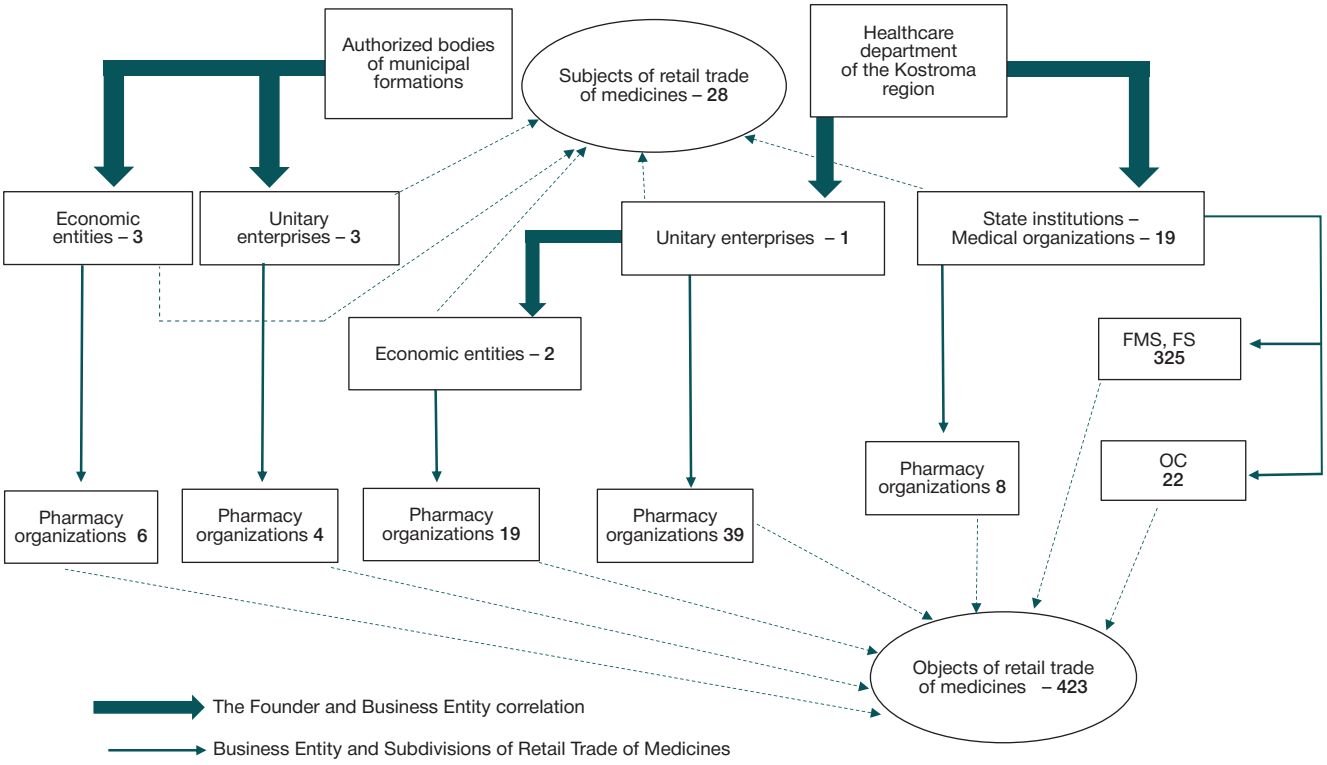

Fig. 2. Legal and organizational structure of the state segment of retail drug market in the Kostroma region

subdivisions of medical organizations, which retail medicines, account for 10% and 47% in the structure of regional market objects, respectively. Thus, in total, the state objects have a share of up to 57% of the whole retail market of medicines in the Kostroma region.

The state segment occupies even a more significant share in municipal entities with rural population (except for municipalities). In this case, state pharmacy organizations and separate subdivisions of medical institutions retailing medicines have totally made 83% of the structure of the mentioned local markets. The analysis is clearly demonstrated in fig. 4.

During analysis of distribution of pharmacy organizations in municipal districts and urban areas of the Kostroma region, a difference in the approaches to development

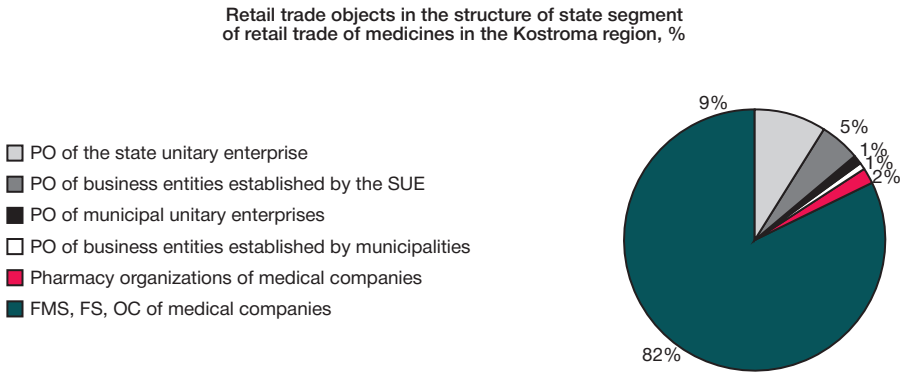

Fig. 3. Distribution of retail trade objects in the structure of state segment of retail trade of medicines in the Kostroma region,%

Table. Distribution of objects of retail sale of medicines in the structure of the pharmaceutical market in the Kostroma region

Pharmaceutical retail market of medicines	Total objects (Dispensing sites of medicines)	Number of pharmacy organizations							Subdivisions of medical organizations that retail drugs	
		Total	Private	Regional market share,%	Share in the total number of pharmacy organizations,%	State	Regional market share,%	Share in the total number of PO	OC, FMS, FS	Regional market share,%
Kostroma region	736	389	314	42.7%	80.7%	75	10%	19.3%	347	47%
Municipalities with rural population	466	119	79	17%	66.4	40	9%	33.6%	347	74%

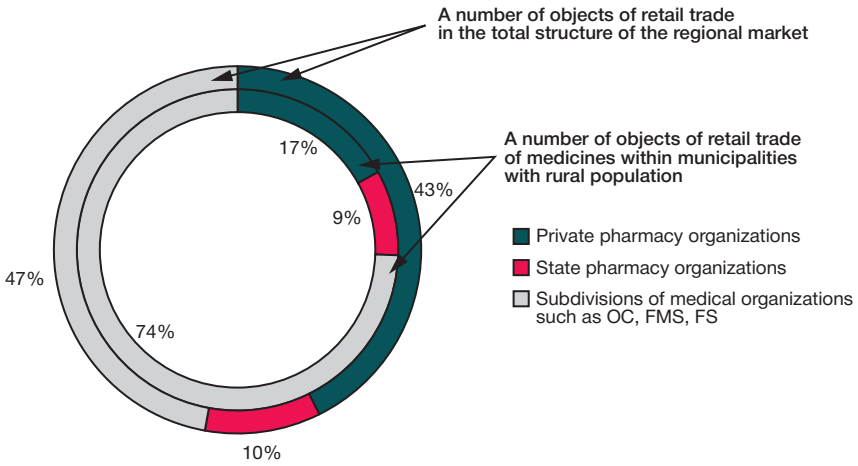

Fig. 4. The structure of the regional retail market of medicines in the Kostroma region by a number of objects of activity

strategies and territorial location among state and private pharmacies of the regional pharmaceutical market has been found out. The obtained results (table, fig. 4) confirm the available regularity of distribution of state pharmacy organizations within the region: the share of their presence in municipal districts with rural population almost corresponds to the share in the retail regional market of medicines (9% and 10%, respectively).

At the same time, private business is presented mainly in urban areas forming the largest market concentration. Thus, the share of private pharmacy organizations in the structure of regional retail market of medicines mainly constitutes 42.7% and decreases to 17% in municipal districts with rural population. So, while moving away from the largest settlements to remote regions with a lower population density, business becomes much less interested in opening the dispensing centers.

Lack of interest of private business in performing an activity within remote and economically unattractive areas results in irregular territorial distribution of private pharmacy organizations on the regional pharmaceutical market. The action of market mechanisms doesn't completely ensure creation of accessible infrastructure of pharmacy servicing of population. This task is mainly solved using the administrative management resource by state pharmacy structures.

There is also a difference in approaches to the activity of state and private pharmacy organizations regarding socially significant services. In the Kostroma region, 30 pharmacy organizations dispensing narcotic drugs and psychotropic substances and 47 organizations providing service to population as far as privileged vacation leave goes have a share of 96% and 93% of state/municipal segment, respectively (fig. 5). Thus, pharmacy organizations of the state segment are presented in all 30 municipal entities and carry a complete load on provision of socially significant services.

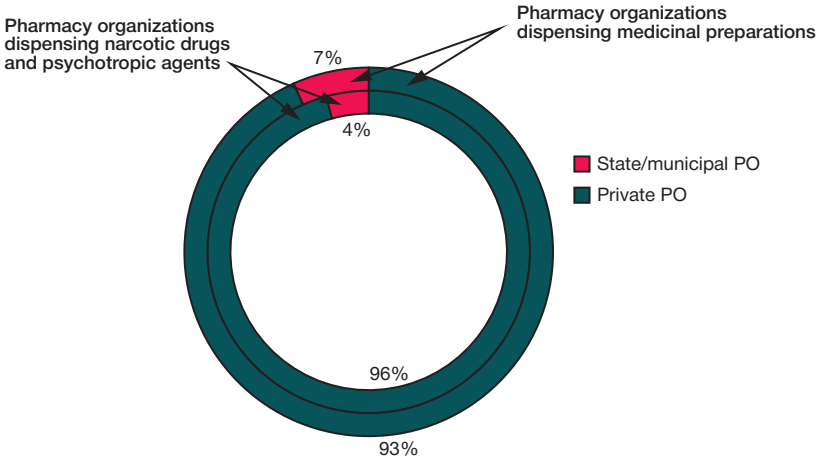

Fig. 5. Provision of socially significant services of medicinal aid to population by a number of activity objects

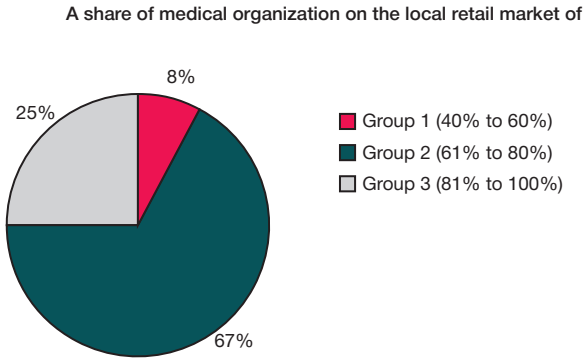

Fig. 6. Distribution of municipal areas by a share of medical organizations on the local drug retail market,%

Increased role of healthcare institutions regarding provision of medicinal aid on the regional drug retail market

Another marked peculiarity of the pharmaceutical market and state segment, in particular, means performing functions of retail sale by non-commercial structures such as public healthcare institutions. In accordance with Federal Law as of April 12, 2021 No. 61-FZ 'Concerning circulation of medicines', retail trade of medicines in rural areas is done by medical organizations if pharmacy organizations are lacking. This confirms a lack of competitive environment and its value under the given conditions.

In accordance with the performed analysis, 19 medical organizations without establishment of a pharmacy organization carry out a retail trade. It constitutes 20% of the total number of retail subjects of medicines within the region. This form of retail trade of medicines is seen in the majority of municipal formations, except for urban areas. From among objects of retail trade of medicines (places of sale), 347 are subdivisions of medical organizations such as OC, FMS, FS (see table), constituting 47% of the total number of places of retail sale within the region and 82% (figure 3) in the structure of the state segment on the regional market of retail trade of medicines [2].

Availability of the state segment on the local markets of retail sale of medicines in 24 municipal regions with rural population constitutes 74% of the total number of places dispensing medicines in these regions. There is a variation of this parameter in different municipal formations depending on the territorial remoteness of regional and district centers, involvement of other market participants in the retail trade of medicines and whether business structures are interested in promotion to the regional settlements. A smaller proportion of medical organizations in the sector of retail trade of medicines is observed for the Pavinsky district (40%), Neisky district (57%), Nerekhta and Manturovsky districts (62%) in relation to other areas. However, a significant contribution to the infrastructure of medicine dispensing is done. Meanwhile, in the Galichsky, Buysky and Kadyysky districts, the retail trade sale of medicines was 100%, 92.8% and 86.4% formed at the expense of healthcare institutions, respectively.

Depending on the share of medical organizations and their separate subdivisions on the local market (FMS, FS, OC), which perform retail sale of medicines, municipal areas (MA) of the Kostroma region can be subdivided into three groups by a number of objects:

- **first group:** MA with a share of medical organizations from 40% to 60% — 2 municipal districts (8% of MA);
- **second group:** MA with a share of medical organizations from 61% to 80% — 16 municipal districts (67% of MA);
- **third group:** MA with a share of medical organizations from 81% to 100% — 6 municipal districts (25% of MP).

Distribution of municipal areas by the share of a presence of objects such as subdivisions of medical organizations in the structure of the local market of retail sale of medicines is presented in figure 6. Based on the analysis results, the second group is the most numerous one (67%). It is represented by municipal areas with a share of objects of medical organizations in the structure of retail sale of medicines from 61% to 80%.

Thus, state medical organizations introduce a significant or principal contribution into formation of the structure of local

retail markets of medicines within the municipal districts with rural areas. Thus, medicinal aid is made affordable to rural population.

Primary targets performed by participants of the state retail market of medicines have differences. Subdivisions of state medical organizations are used to approach provision of medicinal aid to rural population, overcome the issues of territorial and transportation access and irregular social and economic development of the settlements. In their turn, pharmacy organizations within the state segment, which are significantly behind medical organizations by a number of dispensing sites, play an exceptionally significant role on the regional retail market of medicines. They also provide the most comprehensive set of social services in the system of medicinal aid (preferential medication supply, dispense of narcotic drugs and psychotropic substances, preparation of medicines).

In this regard, comprehension and assessment of prospects for development of the structures of the state segments on the regional pharmaceutical market, presence of risks of development associated with the tendencies of legal regulation are of primary importance.

Peculiarities of legal regulation of the activity of state segment organizations on the market of medicinal preparations considering the risks of regulating effect

It should be noted that the value of the state segment has increased not just in the sphere of retail sale of medicines, but also on the pharmaceutical market. Serious risks occurred during the pandemic while solving acute and urgent issues of population and healthcare system supply with medical and pharmaceutical products in large quantities. Conditions of spreading the coronavirus infection, a rapidly growing demand, and an exponential increase in needs resulted both in higher prices for medicines and medical devices, and disbalance in the physical distribution system in the commercial segment of the pharmaceutical market, and emergence of product deficit. It required to take legal, management and organizational measures of state involvement and attraction of public control.

To modernize drug supply, a federal center of planning and organization of drug supply of citizens was established in 2020. It is intended for purchase of medicines to implement the Healthcare National Project, federal programs, National Immunization Schedule, provision of orphan patients, analyze purchase and predict the regional need in medicines as this could prevent possible interruptions in the supply of medicines and form the required reserve beforehand. The center allows to address the issues with current and urgent purchases in the face of diseases in a complex fashion [3]. Here we have an issue of the restored centralized system of drug supply in the most strategically important trends of drug supply.

During the influence of pandemic and economic sanctions, the state segment of regional pharmaceutical markets also underwent the increased load associated with the support of distribution chains and supply of customers and healthcare institutions with medicines. These tasks are mainly solved using state wholesale and retail pharmaceutical enterprises.

At the same time, in accordance with par. 4a of the National plan of competition development that limits establishment of unitary enterprises on competitive markets [4], amendments introduced by Federal Law as of December 27, 2019 No. 485-FZ to the legislation acts entered in force in 2020:

- amendments of Federal Law as of November 14, 2002 No. 161-FZ 'Concerning the state and municipal unitary enterprises' reconsider the targets of establishing unitary enterprises (article 4) and exclude the possibility of establishing such enterprises on competitive markets;
- Federal Law as of July 26, 2006 No. 135-FZ 'Concerning protection of competition' is complemented by article 35.1 'Prohibition to establish unitary enterprises and exercise their activity on competitive markets'.

Unitary enterprises established on competitive markets until January 08, 2020 are subject to elimination or reorganization until January 01, 2025 and, if the decision was not accepted or executed, should be liquidated in a legal proceeding on the claim of the antimonopoly authority.

In accordance with the FAS, restructuring of unitary enterprises into other organizational and legal forms such as a joint stock company or a limited liability company will allow accounting of both the state and municipal property and rental revenue. This will involve a budget revenue increase, whereas involvement of unitary enterprises and their property in the market relations will significantly reduce state expenses and bring additional income to the state [1]. This position is aimed on an increased effectiveness of managing the state (municipal) property. However, the social constituent (functioning of socially significant labor markets including the drug market) is not taken into account in this case.

By 2025, the public and local authorities will have to dissolve unitary enterprises or reorganize them by way of transformation and introducing changes in the organizational and legal status if they intend to save the resource of influence. Thus, the state management bodies will consider an exit of liquidated unitary enterprises from the market as a loss of a serious resource of influence on the regional pharmaceutical market regarding organization of affordable retail sale of medicines and performance of socially significant tasks in the field of drug supply that require a rapid response.

When unitary enterprises are transformed into business corporations, the coordinating role of authorized bodies can be reduced. Moreover, privatization of property and review of leasing obligations can result in closure or reprofiling of certain objects and, as a consequence, loss of structural market units, refusal from some social load and need to search for alternative solutions.

The legislative initiative seen in draft law No. 912246–7 [5], which is associated with the establishment of mobile pharmacies to increase affordability of drug supply, is definitely a justified and necessary measure. It is correlated with the tendencies of organization of primary medical aid at the modern stage, when mobile complexes are widely used. The mobile form still has serious usage-related limitations due to the lack of year-round accessibility on certain territories. It is not an ideal alternative during provision of socially significant functions of medicinal aid to the population. Thus, the mobile form of medicinal supply of the population can be as an addition to the available properly formed infrastructure of pharmacy objects and services.

Thus, reduction of the state segment on the pharmacy market can lead to the following risks:

- worse affordability of medicinal aid in inaccessible and economically unattractive territories;
- improper further possibility of attributing social functions over the private business subjects due to the lack of compellent legal instruments;
- forced increase of the load on medical institutions engaged in provision of drug services as it is necessary to solve social issues in the lack of alternative options.

Complete transfer of the functionality on medical organizations or private business can inevitably result in the

worse quality of services in the area of retail sale of medicines. On the one hand, it happens due to insignificant financial and professional preparedness. On the other hand, it can be explained by reduced motivation and internal liability.

CONCLUSION

The study comprehensively considers development and composite structure of the state segment of the regional drug retail market which includes the objects of activity as part of companies with different organizational and legal forms managed or coordinated by representatives of public entities. A model of the state segment structure was suggested considering the organizational and legal interactions used to examine the regional pharmaceutical market of the Kostroma region.

Distribution of objects within the state segment structure and in the structure of the regional pharmaceutical market was analyzed. The differences in the strategies of functioning and development of the state and private segments of the regional drug retail market have been identified.

Legal preconditions and social and economical conditions of the growing role of healthcare institutions in the system of drug supply of population have been designated.

Controversies in the directions of legal regulation at the modern stage have been found in relation to developmental prospects and significance of the state segment structures. It has been established that the tendencies intensifying participation of the state in the system of drug supply to ensure proper management of budgetary resources and risk prevention were accompanied with previously adopted extra-branch changes of legislation. This could result in reduction of the state segment in economics that would inevitably lead to serious changes in the structure of the pharmaceutical market and redistribution of social load among its participants [2]. In our opinion, this aspect should be designated within industry regulation.

A serious understanding of prospects for functioning of the state segment of retail trade of medicines is required both at the level of regulatory agencies and within the professional community considering the preservation of social services of medicinal aid and decreased risks of negative phenomena on the pharmaceutical market. Apart from establishment of conditions for development of private business and support of entrepreneurship, it is necessary to take into account the value of subjects of the state segment of the pharmaceutical market. Doing this, it is necessary to consider the actual condition and infrastructure of regional markets, economic and professional features of business entities, assessment of the growing role of healthcare institutions in the system of drug supply, and predicted risks from expected changes.

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DEVELOPING THE SYSTEM OF STATE CONTROL OF DRUG QUALITY THROUGH FORMATION OF COMPETENCE CENTERS IN FEDERAL LABORATORIES OF THE INFORMATION CENTER FOR EXPERTISE, ACCOUNTING AND ANALYSIS OF CIRCULATION OF HUMAN MEDICINAL PRODUCTS OF THE FEDERAL SUPERVISORY AGENCY FOR HEALTHCARE OF RUSSIA

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State control over the drug quality is a key component of the healthcare system aimed at provision of patients with safe and effective medicinal products [1]. Stable development of this direction was closely associated with update of testing laboratories, which performed the function, and was characterized as a stable growth of laboratory competencies in the field of not just implementation of new analytical methods, but also in the systemic approach to improvement of skills and knowledge of personnel directly involved in laboratory research. A common approach reflected in accreditation criteria for compliance with GOST ISO 17025 means that the testing laboratory has a plan for internal and external education. However, conventional attitude to this issue does not lead to the desired practical effect. Then the laboratory is urged to find additional ways of development. Formation of competence centers by a certain vector of knowledge on the basis of testing centers can be a perspective option of the systemic approach to updating skills of the personnel. The Yaroslavl branch of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare and basic department of innovative pharmacy of the Yaroslavl State Medical University that successfully uses the basis can serve as examples of such an approach.

Keywords: laboratory of the Federal Supervisory Agency for Healthcare, basic department of innovative pharmacy, HPLC, Raman spectroscopy, GLP

Author contribution: Galeev RR — article concept, study planning; Lileeva EG — literature selection and analysis; Ryzhkova EA — data generalization, text writing; Galeeva EV — data collection, data analysis; Lezhnina NA — data interpretation, preparing a draft of the manuscript.

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РАЗВИТИЕ СИСТЕМЫ ГОСУДАРСТВЕННОГО КОНТРОЛЯ КАЧЕСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ ЧЕРЕЗ ФОРМИРОВАНИЕ ЦЕНТРОВ КОМПЕТЕНЦИЙ В ФЕДЕРАЛЬНЫХ ЛАБОРАТОРИЯХ ФГБУ «ИМЦЭУАОСМП» РОСЗДРАВНАДЗОРА

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Государственный контроль за качеством лекарственных препаратов является одним из основополагающих элементов системы здравоохранения, направленным на обеспечение пациентов безопасными и эффективными лекарственными препаратами [1]. Устойчивое развитие данного направления неразрывно связано с совершенствованием испытательных лабораторий, осуществляющих данную функцию, и выражается в устойчивом увеличении компетенций лабораторий не только в области внедрения новых аналитических методов, но и в системном подходе к улучшению навыков и знаний персонала, непосредственно вовлеченного в процесс проведения лабораторных исследований. Общепринятый подход, отраженный в критериях аккредитации на соответствие ГОСТ ИСО 17025, предусматривает наличие в испытательной лаборатории плана как внешнего, так и внутреннего обучения, однако зачастую формальное отношение к данному вопросу не приносит желаемого практического результата, что побуждает лабораторию искать дополнительные пути развития. Одним из перспективных вариантов системного подхода к совершенствованию навыков персонала может стать формирование центров компетенций по определенному вектору знаний на базе испытательных центов. Примером такого подхода может стать Ярославский филиал ФГБУ «ИМЦЭУАОСМП» Росздравнадзора и базовая кафедра «инновационной фармации» Ярославского Государственного медицинского университета, успешно функционирующая на его базе.

Ключевые слова: лаборатория Росздравнадзора, базовая кафедра инновационной фармации, ВЖЭХ, Раман-спектроскопия, GLP

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The Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare is empowered to conduct tests of quality of medicinal products to detect their compliance with the requirements of pharmacopoeia articles included into the valid edition of the national Pharmacopoeia and Pharmacopoeia of the Eurasian Economic Union as a part of the state task. Twelve equipped laboratory complexes located in Moscow, Krasnoyarsk, Rostov-on-Don, Kazan, Tambov, Gudermes, Kursk, Stavropol, Simferopol, Khabarovsk, Saint-Petersburg and Yekaterinburg formed part of a budgetary institution until March 2021. However, a new

Fig. 1. Solemn opening ceremony of the Yaroslavl branch of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare.

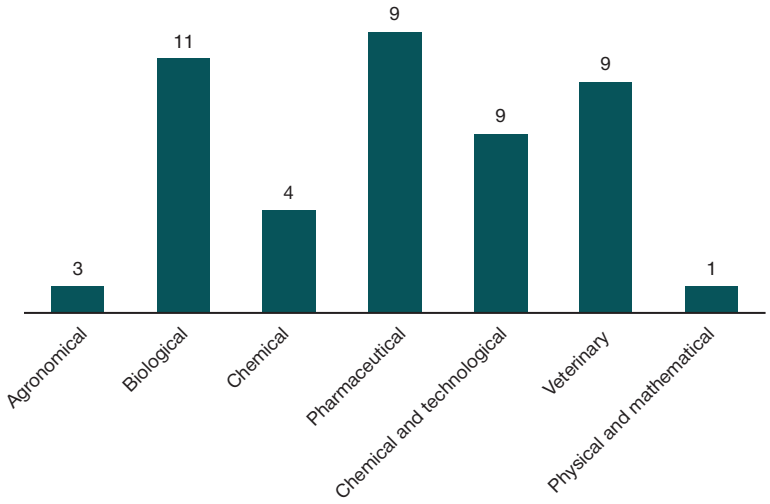

Fig. 2. Diagram of distribution of laboratory employees by their education

thirteenth laboratory was opened in Yaroslavl in March 2021 (fig. 1).

A newly opened laboratory, which is a joint investment project of the Federal Supervisory Agency for Healthcare and Yaroslavl region, was the largest one in the structure of the institution. Total area of the building and adjacent structures was over 7,000 square meters. The complex includes analytical and microbiological laboratories, laboratory of control of quality of immunobiological medicinal preparations, pharmacological laboratory and mass spectrometric center.

Subsequently, a group of Raman spectroscopy and perspective developments working on express methods of analysis of medicinal preparations, including methods of control of medical gases, moved from Kazan to Yaroslavl. The total staff size of the laboratory is 77 people. They are mainly professionals with pharmaceutical, chemical, biological and higher veterinary education (fig. 2). Their average age is 37 years.

Employees of the lab are represented both by young specialists from the Yaroslavl region, and foreign specialists.

The center is equipped with the most up-to-date equipment and engineering systems. They can be used to solve pressing issues and face the future with confidence.

1. BASIC DEPARTMENT OF INNOVATION PHARMACY

Launching of the laboratory was accompanied by signing of an agreement between the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare and Yaroslavl State Medical University. It was marked by the functioning of the basic department of innovative pharmacy on the basis of the branch. The most important activities of the department included tasks of career orientation for students and advanced training of the lab employees and professionals who desire to gain new knowledge through participation in the professional training programs. By October 2022, two educational programs such as ‘Identification of pharmaceutical substances and ready-made medicinal products using non-destructive methods spectral methods of express analysis such as near infrared and Raman spectroscopy. Incoming control over production’ and ‘High-performance liquid chromatography: basis of the method, measurement technique, practicum’ have been developed. Another program named ‘Organization and conduction of preclinical trials in accordance with the national and international rules of GLP’ has been developed and approved as well. The first theoretical

and practical classes were conducted using the approved programs. The results were utilized to take a decision on placement of the theoretical part on the digital educational platform of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare.

Supporting career orientation, the students of the Yaroslavl State Medical University were prepared to defend their theses with regular excursions and practical training that make the students familiar with the activity of the Federal Supervisory Agency for Healthcare in the field of state control of quality of medicinal agents.

The innovative pharmacy basic department became a solid foundation to establish a center of competencies on the basis of the branch that provided the necessary impetus. The impetus was aimed at the systematic development of professional reputation of the newly formed laboratory complex.

2. CENTER OF MASS SPECTROMETRIC ANALYSIS

Due to high cost of equipment, expendable materials and reagents and very high requirements to personnel competence, mass spectrometry failed to become generally recognized during standard procedures of testing the quality of medicinal products. In the majority of pharmacopeial articles to determine product-related impurities, HPLC detectors are used such as a UV–Vis spectrophotometer, fluorometric, refractometric and — in some cases — evaporative light-scattering, conductometric and amperometric detectors. However, when extremely high sensitivity and high selectivity are required, it is difficult to find a detection method, which could be as good as mass-spectrometry coupled with HPLC or GC. The idea was clearly demonstrated while detecting genotoxic mixtures of nitrosamines in preparations of sartans, ranitidine and metformin.

The center was equipped with various types of mass-spectrometers such as HPLC high resolution Q-ToF MC/MC, which allows to deal with complex tasks of protein molecule characterization, including spectrum measurement of intact proteins (fig. 3) and peptide mapping, with the ultra-sensitive triple quadrupole MS/MS system used in qualitative analysis, GC–MS system intended to determine pesticides in medicinal plant material, and inductively coupled plasma mass spectrometer to determine elemental impurities in pharmaceutical substances and excipients.

The center is currently the only separate subdivision of that type in testing labs that perform quality control of medicinal products. Over 25 methods, including methods described in general monographs of the SP of Russia, have been developed and validated during a year and a half.

The center employees are highly qualified in this field of knowledge and actively participate in Russian and international research conferences.

3. THE GROUP OF RAMAN SPECTROSCOPY AND PERSPECTIVE DEVELOPMENTS

The group concentrates mainly on the development of novel methods of quality control of medicinal products including non-destructive express methods and control methods of medical gases. As far as the last ones go, the group uses combined light scattering spectroscopy (Raman spectroscopy), which allows to check the validity of liquid medicinal products, powders and pharmaceutical substances, and — for some products — quantitative analysis in relation to the original specimen.

Scientific interests of the group include not only instrumental method documentation, but also development of new mathematical algorithms to process and analyze spectral data and software, which can effectively deal with novel algorithms [2,3]. The ways of developing reference spectral models used by the Federal Supervisory Agency for Healthcare represent a unique development and have been registered in the Russian Federation.

Software created by the group specialists is based on the use of cloud technologies. They unite several laboratories into one network.

Many years of work within this group resulted in the development of Mini-Ram 532 software and hardware system (fig. 4) actively implemented by the Federal Supervisory Agency for Healthcare within mobile labs to control quality of medicinal products [4–6].

Development of methods of analysis of medical gases, including medical oxygen, represents another activity area of the group. A method of control of medical oxygen quality with gas chromatography and PIA portable gas chromatography complex has been developed (fig. 5). The complex was created jointly with the Russian company based in S. P. Korolev Samara Research University. The method was metrologically certified by the Ural Research Institute of Metrology.

The developed method is used to perform oxygen analysis during several minutes practically by all principal indicators (assess oxygen content, check admixtures of carbon monoxide and dioxide). The method was introduced into the

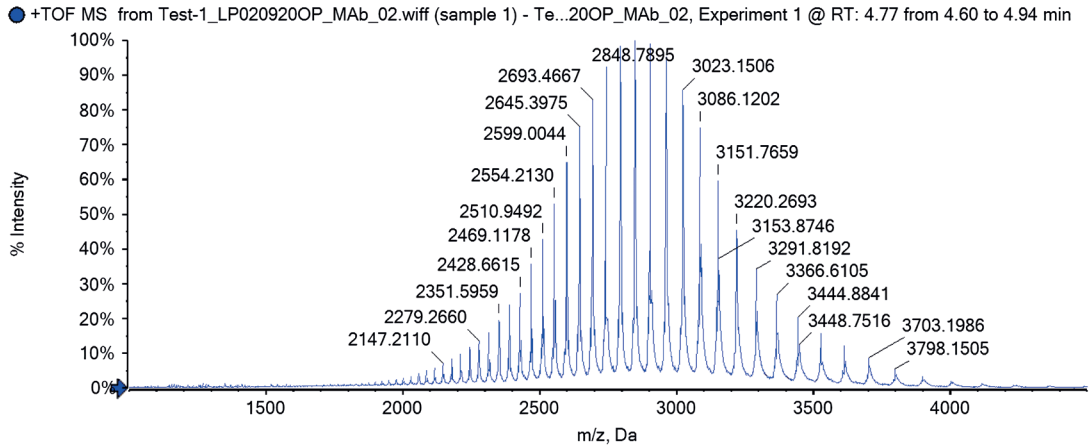

Fig. 3. Mass spectrum of pertuzumab monoclonal antibody

Fig.4. Mini-Ram 532 software and hardware system (SHS), general view

Fig. 5. PIA gas chromatography complex, general view

Pharmacopoeia of Russia in 2020. This allowed to reduce the time spent on analysis of one oxygen series from one day to one hour minimum, including all preparatory works associated with sampling. It is especially important during pandemic when consumption and production of oxygen is increased several hundred times.

Moreover, the method can be used in the mobile lab owing to compactness of the equipment. This addresses the problem of transportation of dangerous cargo including oxygen bottles to the lab and their storage. All branches of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare are supplied with this equipment, and specialists underwent necessary training.

4. PARTICIPATION IN INTERNATIONAL EXPERT COMMITTEES

International activity is an essential part of formation of high competence regarding the issues of quality control of medicinal products due to harmonization of principles and approaches at the level of national and supranational pharmacopeial committees.

Specialists from the testing lab of the Yaroslavl branch of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare are active participants of expert working groups within the European (EDQM), groups 10A, 9, 9G, and American Pharmacopoeia. They also represent interests of the Russian Federation in the International Council on ICH Harmonization.

Several analytical methods included into the valid edition of the European Pharmacopoeia were developed, validated and verified in continuous cooperation with the European Directorate for the Quality of Medicines.

5. CERTIFICATION OF CELL BANKS OF PRODUCERS

The Yaroslavl branch was the third branch within the Yaroslavl branch of the Information Center for Expertise, Accounting and Analysis of Circulation of Human Medicinal Products of the Federal Supervisory Agency for Healthcare of Russia. The laboratory that controls quality of immunobiological medicinal products is included in its structure. This subdivision is intended for quality tests of such medicinal products as vaccines, sera, toxins, anatoxins, monoclonal antibodies, etc. However, specialists quickly mastered a new direction, complex attestation of cell banks of producers.

Requirements to the system assessing quality of cell cultures during manufacture of immunobiological medicinal products are determined considering the need in substrate safety maintenance [7]. Testing methods of cell cultures are determined in the State Pharmacopoeia of Russia XIV (GMP. 1.7.2.0011.15 Requirements to cell culture substrates used in manufacture of immunobiological medicinal products, GMP. 1.7.2.0006.15 Test of viral vaccines for foreign agents) and Decision of the Council of the Eurasian Economic Commission as of November 3, 2016 No. 89 ‘Concerning approval of the Rules of Testing Biological Medicinal Products of the Eurasian Economic Union’.

The majority of necessary methods have already been presented in the lab. However, when the lab started functioning, some specific methods were lacking. Their urgent introduction was required. These methods included genetic sequencing and karyotyping.

Current capabilities of the lab allowed to conduct attestation both of the main, and working cell banks. Until recently, this could have been done in foreign labs only.

The lab employees developed new approaches and methods that will form the basis of theses to be defended at the innovative pharmacy department.

6. SCIENTIFIC ACTIVITY

The innovative pharmacy basic department was the essential element of the lab complex that allowed to amend developmental vectors of the lab and specialists by means of their participation in scientific developments and implementation of possible defense of PhD and doctoral theses.

Scientific researches in the field of bioanalytical studies associated with creation of new assay methods of medicinal products in the blood of patients using the surface-enhanced Raman spectroscopy and in the field of pharmaceutical chemistry associated with creation of express methods of screening the quality of medicinal products and medical gases are actively carried out. 4 topics of PhD theses have been approved.

Achievements in the field of new developments are being actively published both in Russian, and foreign scientific journals.

7. CONCLUSION

Thus, establishment of competence centers with a number of directions related to quality control of medicinal products gives a possibility to move from a simple model of formal reproduction of methods from monographs to a more complicated model. The last one includes a set of activities aimed at formation of high professional reputation of the lab. This is confirmed by an increased amount of consultation and information services in the field of development and validation of new methods provided by the branch (5.074 hours in 2022 as compared with 1.086 hours in 2021).

One of the most important aspects of the selected strategy of the branch development as a competence center was the basic innovative pharmacy department. It was a bridge between the academic environment to the practical use of knowledge accumulated during decision of scientific tasks, on the one hand, and aid in career orientation, on the other hand.

Subsequent plans of the lab development include implementation of a greater number of unique directions associated with the quality testing of medicinal products, attestation of standard samples and working with radiopharmaceuticals.

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ETHICAL ASPECTS OF PHYTOTHERAPY

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The review is devoted to safety issues of herbal medicinal products. Apart from the most known adverse effects such as allergic reactions and irritation ofmucous membranes, use of a number of herbal medicines results in hormonal disturbances, organotoxic reactions and CNS disturbances. The problem of intoxication is pressing in case of uncontrolled administration of herbal remedies, which is often accompanied by a carefree attitude towards them as natural and thus safe agents. This assurance is developed in the result of non-ethical advertising of dietary supplements in mass media. Finally, an important factor of safe therapy is comprehensive accounting of potential herb-herb and herb-drug interactions. The purpose of the article is to attract attention to a weighted attitude towards phytotherapy concerning its safety both in administration of traditional herbal medicinal products by doctors and during self-treatment bypatients.

Key words: phytotherapy, adverse reactions, overdose, drug interactions

Author contribution: Korotaeva MS — data analysis, manuscript preparation; Sidorov AV — concept of publication, editing; Tichonova IG — data selection.

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ЭТИЧЕСКИЕ АСПЕКТЫ ФИТОТЕРАПИИ

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Обзор посвящен вопросам безопасности лекарственных растительных средств. Помимо наиболее известных нежелательных эффектов — аллергических реакций, раздражения слизистых оболочек, при применении целого ряда растительных средств могут возникать гормональные нарушения, органотоксические реакции, расстройства ЦНС. Актуальной является проблема интоксикации при бесконтрольном приеме препаратов растительного происхождения, зачастую обусловленная легкомысленным отношением к ним как «натуральным», а значит безопасным средствам. Такая убежденность возникает в том числе в результате неэтичной рекламы БАД в СМИ. Наконец, немаловажным фактором безопасности терапии является всесторонний учет потенциальных лекарственных взаимодействий фитопрепаратов между собой и с синтетическими лекарственными средствами. Цель статьи — привлечь внимание к более взвешенному отношению к фитотерапии с точки зрения ее безопасности, как при назначении лекарственных препаратов врачами, так и при самолечении пациентами.

Ключевые слова: фитотерапия, нежелательные реакции, передозировка, лекарственные взаимодействия

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Medicinal plants (MP) include wild and cultivated plants used to prevent and treat diseases that affect humans and animals. About 20 thousand of MP are currently used. According to WHO, about 70% of the world population treat herbal remedies as additional or alternative medicine [1]. A significant growth of consumption of MP both in traditional and official medicine has been found during the last years. This growth is due to several factors: over-the-counter sale of herbal medicinal products (HMP), use of MP as part of dietary supplements and affordability, in a number of cases (as compared with synthetic drugs). However, for the majority of phytotherapy apologists, an opinion about safety of plant-derived drugs is a determining factor while selecting a medication.

This can be explained by advertising of these agents and dietary supplements in mass media, which is sometimes far from being ethical. HMP are commonly used by population not by a doctor's prescription, but for self-treatment.

Along with certain advantages HMP have significant disadvantages associated with standards of their quality, safety and therapeutic effectiveness.

The issue of MP safety is of a great practical value, as in the Russian Federation, HMP account for up to 30% of the pharmacy assortment and are dispensed without a prescription [2]. Many consumers of HMP do not consult a doctor regarding safety and effectiveness of these products and take them in an uncontrollable manner, without considering indications and contraindications, concomitant diseases and drug interactions both between the active ingredients of separate plants if several herbal medicines are taken or, for instance, home-made herbal mixtures are used, and with conventional synthetic drugs.

Moreover, manufacture of HMP is associated with potential risks that influence effectiveness and safety of therapy: erroneous identification of MP (during collection, supply of raw material, etc.), raw material contamination (waste products of rodents, insects, pollen of other plants, etc.) or mixtures of similar plants (that are not biologically active at the most), instability of active ingredients, and variability of raw material collection [3].

Extensive experimental and clinical material that characterizes toxicity of certain biologically active substances

contained in MP has been accumulated lately. However, these data are not unified and not included into any national or international regulatory documents [4].

THE ISSUE OF TOLERANCE AND SPECIFIC ADVERSE REACTIONS OF HMP

Allergic reactions belong to the most frequent adverse effects of HMP. An irritant effect produced on the mucous membranes of the GIT and skin is quite common while taking HMP [5].

The MP that contain toxic substances are potentially dangerous. These MP are often included into herbal preparations; some of the preparations contain two potentially toxic substances. For instance, herbal mixtures to treat bronchopulmonary diseases can contain both marsh Labrador tea (Ledum palustre) and coltsfoot (Tussilago farfara). Even therapeutic doses of Ledole contained in marsh Labrador tea essential oils can produce an irritant effect and result in inflammation of the GIT mucous membrane [6]. Pyrrolizidine alkaloids within coltsfoot have a pronounced hepatotoxic effect [7]. Some mixtures used for therapy of gastrointestinal diseases contain three potentially toxic MP: absinthe (thujone), sweet flag (β-azarone) and peppermint (pulegone at minor concentrations). For instance, owing to thujone, absinthe can be responsible for vomiting, gastric and intestinal spasms. β-azarone, which is contained in sweet flag rhizome essential oils, has mutagenic and cancerogenic properties, whereas pulegone produces a hepatotoxic action [7]. It is dangerous because the majority of these substances are accumulated in the body, and their toxic effect is developed slowly [2].

Over 40 currently known medicinal herbs can cause hormonal changes in the body. Only some of them are used to produce medicinal agents and dietary supplements. In particular, products based on Pygeum africanum, Serenoa repens, Vitex agnus-castus and Cimicifuga racemose are used to treat endocrine disturbances and diseases such as menstrual disorders, premenstrual syndrome, mastodynia, blood ciculation and autonomic dysfunction during pre- and post-menopause, prostatic adenoma and prostatitis. In other medicinal products hormonal activity is taken as an adverse effect. Thus, herbs with oxytocin-like activity induce abortion (Verbena officinalis, Harpagophytum procumbens, Cytisus scoparius); medicinal herbs with corticosteroid activity increase blood pressure and cause electrolyte disbalance (Panax ginseng, Eleutherococcus senticosus, Glycyrrhiza glabra, Myrica cerifera); plants with a predominant estrogenic activity can cause microcirculation disturbances and thromboembolic complications (Anisum vulgare, Asclepias tuberosa, Trifolium pratense, Ferula foetida, Glycine max, Humulus lupulus, Cimicifuga racemosa) [8].

Intrinsic hormonal activity of such plants as Anisum vulgare, Trigonella foenum-graecum, Verbena officinalis, Harpagophytum procumbens, Cytisus scoparius, Ferula assa-foetida is found in *in vitro* and *in vivo* experiments. Hormonal activity of Panax ginseng, Trifolium pratense, Pygeum africanum, Serenoa repens, Glycyrrhiza glabra, Glycine max, Humulus lupulus, Cimicifuga racemose and Eleutherococcus senticosus is confirmed both on animals and in clinical studies [9, 10].

It should be noted that some plants with intrinsic hormonal activity are widely used in food industry as well. For instance, humulus is widely used in brewing while fenugreek in cheese-making.

Some plants contain substances with a direct organotoxic activity. For instance, Ledum palustre, Berberis vulgaris and Rúta graveolens possess nephrotoxicity. Artemisia absinthium, Petroselinum crispum and Dryopteris filix-mas have a neurotoxic action [2]. It means that patients have to be informed about the adverse effects by medical specialists.

The MP, that cause severe and life-threatening reactions or those with experimentally established cancerogenic, mutagenic and embryotoxic effects give rise to serious security problems. Thus, in accordance with available data, Acorus calamus, Aristolochia franchi, Tussilago farfara, Symphytum officinale, Centella asiatica have a potential cancerogenic effect [11]. These adverse reactions are developed slowly (for several weeks-months-years) and do not have clinically pronounced symptoms during the development.

OVERDOSAGE OF HERBAL MEDICINAL PRODUCTS

Adverse effects of MP are often developed in case of overdosage of their active ingredients. Overdosage of the majority HMP is characterized by typical mild general toxic adverse reactions: headache, nausea, vomiting, etc. However, long-term intake of increased dosages of such popular MP as lavender and ginger can result in more serious consequences such as CNS depression and respiration, seizures and cardiac arrythmias.

Overdosage of other HMP causes specific complications. For instance, uncontrolled administration of turmeric preparations (Curcuma longa) can lead to internal bleedings. Long term administration of alder buckthorn bark extract (Frangula alnus) can result in hypokalemia, reduced bowel motility, albuminuria and hematuria. If large dosages of stimulating HMP, for instance, ginseng extract/tincture (Panax ginseng), are used, arterial hypertension, increased excitability and insomnia can evolve [12]. Large doses of marsh Labrador tea (Ledum palustre) inhibit CNS and cause spastic paralyses, including respiratory paralysis [6].

Long-term use of absinthe (Artemisia absinthium) in doses higher than therapeutic ones can cause seizures and hallucinations [7].

Liquorice (Glycyrrhiza gabra) is a popular plant used in conventional and traditional folk medicine as an expectorant. If the recommended dosages are exceeded and taken on a long-term basis, specific adverse effects (hyperaldosteronism (elevation in BP, edema, hypokalemia), encephalopathy, muscular weakness, retinopathy, cardiac dysfunction) can evolve [12].

DRUG INTERACTIONS OF HERBAL MEDICINAL PRODUCTS

At least 30% of patients receiving long-term pharmacotherapy take additional HMP. Only 20% of them inform their attending physician thereof. Up to 70% of patients who used phytotherapy are not informed of possible adverse reactions, including the ones occurring due to drug interactions. Serious adverse events occur in 16% of cases. Nevertheless, no significant data about the frequency and nature of drug interactions with HMP are available. A physician should know that at least 80 MPs have clinically significant interactions with conventional drugs [13]. At the same time, doctors are not even aware of a possible herb-drug interactions due to a number of reasons. Many qualified doctors lack sufficient knowledge about HMP pharmacology, and, in particular, their potential drug interactions. Moreover, while collecting medication history, doctors often ignore questions about HMP intake, whereas patients do not inform a doctor hereof proactively [14].

Additional issues can be associated with the nature of HMP, for instance, content of mixtures with an additional (not expected) pharmacological activity (see above).

HMPs have both pharmacodynamic (without a change in the substance concentration in the blood) and pharmacokinetic (with a change in the substance concentration in the blood) drug interactions with synthetic drugs. The favorable or unfavorable drug interactions result in a stronger or weaker effect of a drug taken along with the HMP.

The capability of a synergic action of MP and conventional medicinal agents is used during manufacture of combined preparations and expectorants, in particular. For instance, a combination of ambroxol hydrochloride, sodium bicarbonate, sodium glycyrrhizinate, and thermopsis dry extract in a medicinal product sold under the trade name "Codelac Broncho" in Russia possesses expectorant and anti-inflammatory action. Similarly, administration of separate drugs of ambroxol or bromhexine in combination with HMP of althea, thyme and ivy, etc. to intensify an expectorant action is an example of beneficial pharmacodynamic interaction [15]. On the contrary, administration of expectorant mixtures along with antitussive drugs, especially the ones that significantly suppress the cough center (codeine, butamirate), is an example of antagonistic interaction and irrational therapy of bronchitis, which can be complicated with "bronchi waterlogging". Another example of pharmacodynamic antagonism is simultaneous administration of HMP obtained from plants with a hemostatic action (stinging nettle (Urtica dioica), shepherd's purse (Capsella bursa-pastoris), great burnet (Sanguisorba officinalis) and antithrombotic for instance, acetylsalicylic acid to prevent thrombosis [14].

Pharmacokinetic interactions of HMP with conventional drugs can occur at any stage (absorption, distribution, metabolism and excretion). However, drug interactions during metabolism and biotransformation enzymes (mainly, cytochromes) modulation are of the greatest value. CYP1, CYP2, CYP3 and CYP4 cytochromes are most involved in drug metabolism. CYP3A4 isoform prevails and metabolizes up to 60% of drugs [16].

It is known that St. John's wort (Hypericum) can induce at least two isoforms of P450 (CYP3A4, CYP2C9) owing to hyperforin [17, 18]. On the contrary, echinacea inhibits the microsomal system (CYP1A, CYP2C9, CYP3A4) [19]. These properties of the MP can be of a clinical significance in concomitant administration of HMP with CYP substrates, of which there are several hundreds in various therapeutic areas. Increased activity (induction) of cytochromes will result in accelerated metabolism of CYP substrates and a decrease of its effective plasma concentration. Inhibited activity of cytochromes can slow down metabolism of a drug and increase its plasma concertation leading to overdosage symptoms.

For instance, concomitant administration of HMP containing ginkgo (Ginkgo biloba) with warfarin or clopidogrel can lead to an excessive increase of plasma concentrations of the drugs and bleedings [13]. It is necessary to take into account these interactions in patients with subsequent surgeries. On the contrary, combined administration of ginseng or hypericum with warfarin can decrease warfarin plasma concentration and increase the risk of thrombotic complications.

Another important but underestimated mechanism of pharmacokinetic interactions is represented by the influence on activity of P-glycoprotein, a transporter of xenobiotics out of cells into the extracellular environment. In particular, P-glycoprotein releases drugs from an enterocyte back into the intestinal lumen and from the cerebral capillary endothelium back into blood. Inhibition of P-glycoprotein results in increased absorption of its substrates from the intestine and increases their penetration into the brain. Induction of P-glycoprotein causes opposite consequences. For instance, St. John's wort, which is a known inductor of P450, is also an inductor of P-glycoprotein. In particular, it can decrease absorption of oxycodone from the GIT and accelerate its metabolism. This finally reduces the analgesic effect [20]. Amitriptyline is another drug, which is a substrate of both CYP3A4 and intestinal P-glycoprotein. Amitriptyline plasma concentration may be reduced in concomitant administration with St. John's wort (herbal antidepressant) when it's required to accelerate or intensify a therapeutic effect [21].

It should be noted that risk factors of adverse effects observed when HMP are administered together with conventional drugs include age (children and elderly), concomitant diseases (especially liver or kidneys failure), polypharmacy (unjustified use of five and more medicinal products), pregnancy and lactation.

CONCLUSION

The current situation makes it necessary to attract attention and use a complex of measures that increase safety of phytotherapy. First, HMP leaflets should contain unified sections describing safety of the drug including all established adverse reactions, contraindications, warnings and drug interactions in detail. This is especially true for herbal mixtures' leaflets, which contain a few or no adverse effects or lack data about their possible administration together with other medicinal products. Instructions for use of HMP should include the indications solely based on clinical data which are obtained using criteria of evidence-based medicine (placebo-controlled or comparative clinical trials). Second, there is a need in more stringent requirements to advertising of herbal medicines and dietary supplements with obligatory detailed covering of safety issues not limited to a disclaimer about required consultations of a doctor and/or potential harm to health. Third, educational programs have to be updated and increased attention to the issues of safety of phytotherapy is required when doctors and pharmaceutical workers are being educated.

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