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Pharmacy Compounding Regulation in the United Kingdom

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Pharmaceutical practice of advanced regulatory healthcare systems places high demands on the quality and safety of medicines, especially on compounding drugs by pharmacies. The United Kingdom is one of the countries with a developed system of legal regulation of drug treatment, which is based on the principles of effective management and is aimed not only at following formal procedures, but also at ensuring the ultimate goals, namely patient safety, quality of manufactured drugs and effectiveness of pharmaceutical processes.

The aim. To identify the key elements of the British system of regulation of drugs compounding by pharmacies, to assess their applicability in other legal systems and to form promising directions for improving Russian legislation.

Materials and methods. The study based on analysis of the UK regulatory framework governing circulation of medicines, as well as documents from government agencies and regulatory agencies. Comparative legal, content analysis, a systematic approach, analytical and empirical methods were used.

Results. Pharmaceutical activity is regulated by the General Pharmaceutical Council, which develops standards and guidelines that are binding. The production of medicines is carried out within the framework of a licensing system and is subject to the principles of good practices. The British system is based on a model of effective regulation, where the emphasis is on achieving targeted results rather than strictly following procedures. There is a separate license for the production of special drugs designed for a specific patient.

Conclusion. Legal and regulatory systems for manufacturing of medicines in the UK demonstrates high degree of harmonization with international standards, including GMP and PIC/S recommendations. It can serve as a model for improving legislation in other countries, including the Russian Federation, in terms of developing and implementing a unified system of regulatory support for manufacturing of medicines, including introduction of adapted GMP requirements into of pharmaceutical medicine manufacturing practice — good practices for the preparation of medicinal products.

Keywords: drugs compounding; compounding pharmacies; personalized medicine; Great Britain; good pharmacy practice; extemporaneously compounded medicines

Abbreviations: IPP — intra-pharmacy preparation; RMP — registered medicinal product; EAEU — Eurasian Economic Union; DF — dosage form; SOP — Standard operating procedure; ECM — extemporaneously compounded medicines; SMP — special medicinal product; GMP — Good manufacturing practices; BPh — British Pharmacopoeia; GPhM — General Pharmacopoeia Monograph; PhM — Pharmacopoeia Monograph.

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Нормативное правовое регулирование изготовления лекарственных препаратов аптечными организациями в Великобритании

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Фармацевтическая практика передовых регуляторных систем здравоохранения предъявляет высокие требования к качеству и безопасности лекарственных препаратов для медицинского применения (ЛП), особенно при их изготовлении аптечными организациями (АО). Великобритания представляет собой одну из стран с развитой системой правового регулирования обращения лекарственных средств (ЛС), которая основана на принципах результативного управления и направлена не только на соблюдение формальных процедур, но и на обеспечение конечных целей, а именно — безопасность для пациента, качество изготовленных ЛП и эффективность процессов осуществления фармацевтической деятельности.

Цель. Выявить ключевые элементы британской системы регулирования аптечного изготовления лекарственных препаратов, оценить их применимость в других правовых системах и сформировать перспективные направления совершенствования российского законодательства.

Материалы и методы. Исследование проведено на основе анализа нормативной правовой базы Великобритании, регулирующей обращение ЛС, а также документов государственных органов и профильных агентств. Применялись сравнительно-правовой, контент-анализ, системный подход, аналитический и эмпирический методы.

Результаты. Фармацевтическая деятельность регулируется Генеральным фармацевтическим советом, который разрабатывает стандарты и руководства, обязательные для исполнения. Изготовление ЛП осуществляется в рамках системы лицензирования и подчиняется принципам надлежащих практик. Британская система основана на модели результативного регулирования, где акцент делается на достижении целевых результатов, а не на формальном соблюдении процедур. Существует отдельная лицензия на производство специальных ЛП, предназначенных для конкретного пациента.

Заключение. Система правового регулирования изготовления ЛП в Великобритании демонстрирует высокую степень гармонизации с международными стандартами, включая GMP и рекомендации PIC/S. Она может служить моделью для совершенствования законодательства в других странах, в том числе в Российской Федерации в аспекте разработки и внедрения единой системы нормативного обеспечения деятельности по изготовлению ЛП, включающей установление «адаптированных» требований GMP в практику аптечного изготовления ЛП — надлежащей практики изготовления ЛП.

Ключевые слова: изготовление лекарственных препаратов; производственные аптеки; персонифицированная медицина; Великобритания; надлежащая аптечная практика; экстемпоральные лекарственные препараты

Список сокращений: АО — аптечная организация; ВАЗ — внутриаптечная заготовка; ГЛФ — зарегистрированный лекарственный препарат; ЕАЭС — Евразийский экономический союз; ЛП — лекарственный препарат; ЛС — лекарственное средство; ЛФ — лекарственная форма; СОП — Стандартная операционная процедура; МО — Медицинская организация; ЭЛП — экстемпоральный лекарственный препарат; СЛП — специальный лекарственный препарат; GMP — Надлежащая производственная практика; БФ — Британская фармакопея; ОФС — общая фармакопейная статья; ФС —фармакопейная статья.

INTRODUCTION

Pharmaceutical practice in developed regulatory systems in the healthcare sector places high demands on ensuring the quality and safety of medicines, especially in cases of prescribing and compounding of medicines for medical by pharmacies. According to some studies, in addition to numerous physical, chemical, instrumental, and microbiological tests, which are most common in the quality control of extemporaneous drugs, it also seems advisable to implement additional control measures to improve the quality level of safety guarantees [1–3].

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Today, there is an special interest in the activity of drugs compounding at various levels of the professional community. As part of the current tasks to improve the main elements of the regulatory legal regulation of drugs compounding, it is fundamentally important to ensure the transition from the current rules of the compounding and dispensing of drugs to the harmonized good compounding practice [4], opening up new prospects for the development of pharmaceutical infrastructure. Its provisions should meet the principles of applicability to any type of drugs that belongs to the segment of personalized medicine, high-tech healthcare, and health-saving technologies, as well as take into account the current features and processes of compounding pharmacies operating in Russia. At the same time, modern pharmaceutical practices require pharmacies to develop competencies in the field of development, testing, mastering, and implementation of advanced and most important technologies for the compounding of drugs[1] [5, 6].

The United Kingdom of Great Britain and Northern Ireland (hereinafter referred to as "Great Britain," "United Kingdom," "England," "Britain") is one of the countries with a developed regulatory system, where the regulatory legal framework combines the principles of precedent, parliamentarism, and constitutional customs (traditionally oriented legislation), including modern approaches to the provision of pharmaceutical care [7, 8]. The legal regulation of the drugs compounding in Great Britain is based on the principles of effective management, which implies an emphasis not only on compliance with formal procedures, but also on achieving the ultimate goals — patient safety, the quality of extemporaneously compounded medicines (hereinafter referred to as "ECMs"), and the efficiency of processes.

THE AIM. To identify the key elements of the British system for regulating the pharmacy compounding of drugs, to assess their applicability in other legal systems, and to form promising directions for improving Russian legislation. The latter is an urgent task in connection with the active discussion of the future of compounding pharmacies in the Russian Federation, including issues related to the implementation of good compounding and dispensing practice[2] of drugs [1, 9], the development and implementation of new provisions of the State Pharmacopoeia of the Russian Federation XV edition [10, 11], which should take into account modern international approaches and opportunities of pharmaceutical practice [12].

MATERIALS AND METHODS

The object of the study was the regulatory legal documents of Great Britain regulating the sphere of circulation of medicines, as well as documents of state bodies and specialized agencies of Britain (https://www.legislation.gov.uk/ — official archive and publishing house of the Government of Great Britain; https://www.parliament.uk/ — official website of the Parliament of Great Britain).

The United Kingdom is a state consisting of England, Wales, Scotland, and Northern Ireland. Naturally, each of these countries has common legislative norms on various issues, including features and (or) exceptions that will not be mentioned in this manuscript and are accepted as irrelevant.

This work is a continuation of a series of scientific research by the authors devoted to the issues of regulatory legal regulation of the drugs compounding in world healthcare systems, where the main legislative imperatives of the named activity were consistently studied (including issues of direct circulation of compounded drugs): at the supranational level — in the European Union (hereinafter referred to as "EU") [13], at the national level — in the USA [14], Germany [15–17], Latvia [18], the Netherlands [19], BRICS countries [12] and the CIS [13], as well as the Russian Federation [20–22].

Starting to study the regulatory legal regulation of the drugs compounding in the United Kingdom, it is necessary to describe the logic of the formation of English legislation, where the following are distinguished[3, 4]:

1. Constitutional documents (un-codified constitution):
   - Act of Settlement, 1701;
   - Bill of Rights, 1689.
2. Primary legislation (acts of parliament):
   - Employment Rights Act, 1996;
   - Equality Act, 2010.
3. Secondary legislation issued on the basis of primary legislation as part of (documents of the UK Government and its ministries):
   - Orders: The Companies (Miscellaneous Reporting) Order, 2018;

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[2] SPCFU's participation in Pharmaceutical Treatment 2025. Available from: https://clck.ru/3MXAC6. Russian

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[4] Partington M. Introduction to the English Legal System 2018–19; Oxford University Press; 2018.

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- Regulations: The Working Time Regulations, 1998;
- Rules: The Immigration Rules, 2023.

4. Guidance and Standards:
   - Fundamental Standards of the Care Quality Commission.

The main research method was comparative legal analysis, which allowed us to identify the features of regulation of compounding of drugs by pharmacies in England and to correlate them with similar approaches in other countries. Content analysis of documents ensured the systematization of legal norms concerning the requirements of licensing, quality control, and distribution of responsibility in compounding of drugs by pharmacies. A systematic approach made it possible to consider the institution of drugs compounding in the context of the entire procedure for the circulation of medicines, to assess the role of professional self-regulatory organizations, and to identify approaches in public administration, including those based on international standards. The analytical method was applied to interpret the requirements for personnel, premises, equipment, and processes of drugs compounding. The empirical method consisted of studying practical examples of the implementation of legal norms. The comprehensive application of these methods allowed us to comprehensively consider the subject of the study and formulate reasonable conclusions.

In this work, an analysis of a wide range of relevant sources was carried out and information was obtained from regulatory acts regulating the activities of compounding pharmacies in Great Britain, which was implemented by the bibliometric method.

Information from various sources was used as materials. In the part of the analysis of regulatory legal documents were used: the electronic fund of regulatory technical and regulatory legal information of the Codex Consortium, the legal reference system of Great Britain Legislation.gov.uk. For analyze of relevant sources of information and data from search engines were used: PubMed, the eLIBRARY.RU, Russian National Library, National Electronic Library, and Google Academy. The search was carried out using the next key queries in English: “medicine”, “extemporaneous”, “compounded”, “drug formulations”, “pharmacy”, “compounding”, “drug”. The selection of literature was carried out for the period from 1968 to 2023. The choice of the period is due to historical events and the beginning of the active development of the activity of drugs compounding in the Soviet Union. The search of literature was in Russian and English.

RESULTS AND DISCUSSION

The main regulatory legal documents that regulate the circulation of medicines in Great Britain are the Medicines Act of October 25, 1968 (hereinafter referred to as the “English Law”)[5] and the Human Medicines Regulations of July 19, 2012 (hereinafter referred to as the “English Rules”)[6], where the word “preparation” is used in relation to the compounding of medicines, similar to that in the European Union (EU).

Key regulators in the market of medicines circulation in Great Britain

The structure of the Government of Great Britain includes[7, 8]:

1. The Department[9] of Health and Social Care [23], responsible for developing public policy in the field of healthcare. The subordinate organization is the Medicines and Healthcare products Regulatory Agency (hereinafter referred to as “MHRA”), which issues licenses to compounding of medicines, wholesale companies, pharmacovigilance, inspection of production sites for compliance with the rules of Good Manufacturing Practice (hereinafter referred to as “GMP”), Good Distribution Practice (hereinafter referred to as “GDP”)[10], and other functions.
2. The Department for Business and Trade[11], responsible, among other things, for the development of the pharmaceutical industry and international trade.

The professional activity of pharmaceutical and medical workers is regulated by independent regulatory bodies in the form of the General Pharmaceutical Council (hereinafter referred to as the “Pharmaceutical Council”)[12] and the General Medical Council[13], which were created by the “Pharmacy Order” No. 231 of February 10, 2010 (hereinafter referred to as the “Pharmacy Order”)[14] and the Medical Act[15] of July 26,

[5] Medicines Act 1968. Available from: https://clck.ru/3MEQvU
[6] The Human Medicines Regulations 2012. Available from: https://clck.ru/3MEfon
[7] National Health Service Act 2006. Available from: https://clck.ru/3MEfqG
[8] Health and Social Care Act 2012. Available from: https://clck.ru/3MEfrB
[9] In the United Kingdom, the words “department” and “ministry” are synonymous due to the historical development of public administration. Russian
[10] Medicines: good manufacturing practice and good distribution practice. Available from: https://clck. ru/3MkHF8
[11] Department for Business & Trade. Available from: https://clck.ru/3MEfsw
[12] General Pharmaceutical Council. Available from: https://www.pharmacyregulation.org/
[13] General Medical Council. Available from: https://clck.ru/3MkHSS
[14] The Pharmacy Order 2010. Available from: https://clck.ru/3MEftn
[15] Medical Act 1983. Available from: https://clck.ru/3MEfuw

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1983, respectively. According to these regulatory legal documents, these independent bodies are accountable to the Parliament of the United Kingdom, but act autonomously.

The National Health Service of Great Britain (hereinafter referred to as "NHS")[16] operates on the territory of the United Kingdom. A formed state healthcare system, created in 1948 and based on the principles of free access to medical services, the financing of which is carried out from taxes paid. The NHS covers the entire territory of Britain and consists of four autonomous but interconnected systems — in England, Scotland, Wales, and Northern Ireland. The system provides access to a wide range of services — from primary healthcare to highly specialized treatment in hospitals [24, 25].

Licensing of pharmaceutical activity

According to the English Rules, there are three main types of activity that are subject to separate licensing procedures:

- Retail Pharmacy Licence;
- Wholesale Dealer Licence;
- Manufacturing Licence.

In the United Kingdom, separate certificates of compliance with GMP or GDP requirements are not issued — the very presence of a wholesale or production license implies that the licensee complies with these rules.

However, the legislation of Great Britain on the circulation of medicines does not contain specific definitions of these types of activity.

Thus, section 8 of the English Rules defines retail pharmacy business, which includes the retail sale of drugs that are not subject to "free sale".

Section 5 of the English Rules presents a classification of drugs:

1. Prescription Only Medicine (hereinafter referred to as "POM").
2. Pharmacy Medicine (hereinafter referred to as "PM") dispensed without a prescription, but only in pharmacies.
3. Available for "free sale" (General Sale List; for example, in supermarkets, hereinafter referred to as "GSL").

The regulation of wholesale trade in medicines is covered in section 18 of the English Rules, where it includes the supply of drugs to medical organizations (hereinafter referred to as "MOs"), as well as other subjects of medicines circulation for the purposes of subsequent resale. However, manufacturers of medicines, when directly selling their products to pharmacies and MOs, do not have to obtain a wholesale license and can carry out supplies under a production license, which is due to the presence in GMP of instructions on compliance with GDP rules (Fig. 1).

The regulation of the activity of pharmacies is carried out according to standards and guidelines that are developed and published by the Pharmaceutical Council. The resulting licensing scheme in the field of medicines circulation is presented in Figure 2.

In accordance with sections 22, 167, as well as paragraphs 14, 22, 37 of Appendix No. 4 of the English Rules, a special license for the manufacturing (Manufacturing Specials Licence) is distinguished [26]. This type of license is intended for the production of "special" medicines (Special Medicines; hereinafter referred to as "SMs") [27], which are produced according to an individual technical specification provided by a doctor, dentist, or pharmaceutical worker and are intended for use by a specific patient, for the effectiveness of treatment of which the above-mentioned specialist bears direct responsibility.

This type of activity is separate and does not require the presence of a "standard" license for the production of drugs, while the compounding of SMs must comply with GMP requirements. There is also a separate MHRA guide for manufacturers of SMs[17], which gives instructions on the interpretation of individual provisions of GMP in relation to the specifics of the products being compounded. This approach is identical in the organization of work of 503B type pharmacies in the USA [28–30], where, as is known, such organizations must comply with GMP requirements, but a separate FDA guide introduces exceptions to these rules. That is, formally, compliance with GMP[18, 19] is required, but not for the entire scope of requirements [12].

SMs are supplied to MOs, where they were prescribed to the patient, at the same time, the possibility and the right to move the named products between Great Britain and Northern Ireland is established. In addition, MHRA has developed a special document on the distribution of SMPs for such cases[20] (Fig. 3).

[16] NHS website for England. Available from: https://www.nhs.uk/

[17] Guidance for 'specials' manufacturers. Available from: https://clck.ru/3MZb58

[18] Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry. Available from: https://clck.ru/3MkGfv

[19] Questions and Answers on Current Good Manufacturing Practice Requirements. Control of Components and Drug Product Containers and Closures. Available from: https://clck.ru/3MkGiE

[20] Medicines and Healthcare Products Regulatory Agency. The supply of unlicensed medicinal products («specials»); MHRA Guidance Note 14; 2014.

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Key features of the legislation on the compounding of medicines

In accordance with part 4 of the English Law, a legal basis was established at the legislative level for regulating retail pharmaceutical activity, including the provision of services for dispensing and drugs compounding.

However, most of the original provisions of this law were repealed or replaced after the entry into force of the English Rules — a regulatory legal document that, at the time of the study, plays a central role both in practical application and in the administrative enforcement of pharmaceutical legislation. Despite this, the English Law remains the legal basis on which modern rules are developed and operate. Many key principles noted in this document are relevant and formed the basis of the modern system of regulation of medicines circulation in the territory of the United Kingdom.

According to section 10 of the English Law, it is not required to obtain a production license for the following actions in pharmacies and MOs:

- compounding of drugs;
- intra-pharmacy packaging of registered medicines (hereinafter referred to as “RMs”).

Such types of activity are carried out exclusively by a pharmacist[21] and (or) under his supervision and can be carried out by pharmacies under a pharmaceutical license, as well as by MOs under a medical license.

In addition, section 10 of the English Law provides an exhaustive list of grounds for the drugs compounding and intra-pharmacy packaging of RMs:

- compounding and intra-pharmacy packaging of MPs are carried out according to a doctor’s prescription for a specific patient;
- compounding and intra-pharmacy packaging of medicines are carried out in the form of intra-pharmacy preparation (hereinafter referred to as “IPP”) for subsequent dispensing according to a doctor’s prescription;
- compounding of drugs at the request of an “individual” [15, 16] for medicines subject to over-the-counter dispensing (PM, GLS);
- drugs compounded by pharmacy are not subject to supply to MOs and can be dispensed to the patient only according to a doctor’s prescription and (or) on the basis of a request from an “individual”, i.e. supply to MOs can only be carried out for SMs, if there is a special license for the compounding of drugs.

In accordance with sections 69, 70, and 71 of the English Law, retail pharmaceutical activity can be carried out either by an individual or by a legal entity (body corporate) [31], and for each of these cases, its own requirements are established for the appointment of persons responsible for pharmaceutical activity.

If pharmaceutical activity is carried out by an individual (analogous to an individual entrepreneur in Russia), then for each address of pharmaceutical activity, a Responsible Pharmacist must be appointed, who is obliged to monitor compliance with pharmaceutical law on a daily basis. The name of the responsible pharmacist and his registration number must be placed in an accessible (visible) place of each pharmacy. He bears personal legal responsibility for compliance with standards when dispensing drug at his address of activity.

If pharmaceutical activity is carried out by a legal entity, then according to sections 69 and 70 of the English Law, a mandatory condition is the presence of a Superintendent Pharmacist [32], who is responsible for all pharmaceutical activity of the company. This specialist must be a pharmacist and be responsible for conducting business in all pharmacies owned by the company. At the same time, for each address of pharmaceutical activity, a responsible pharmacist must be appointed, who can be either the superintendent himself or another pharmacist acting under his guidance. Thus, the superintendent provides overall control and compliance with standards throughout the network, while responsible pharmacists bear operational responsibility for the pharmaceutical services provided and the work performed by specific pharmacies.

It is also worth noting here that English legislation uses the term “Assembling a Medicinal Product” [33], which also includes intra-pharmacy packaging of RMs, as well as: “relabeling of medicines” and “packaging of medicines” with other components (for example, syringes, dispensers). At the same time, the direct process of “assembly” of drug consists in the fact that there should be no qualitative and quantitative change in the drug or its dosage form (hereinafter referred to as “DF”).

According to part 1 of the English Rules, EMs and packaged RMs are not subject to state registration in the territory of Great Britain. In the context of the cycle of works by the authors of this study, the latter has a significant role in view of the presence of legal conflicts in the procurement of EMs and packaged RMs, since in Russian legislation [13, 34]:

[21] In the UK, there are pharmacists (higher pharmaceutical education — 4 years of study) and pharmaceutical technicians (secondary pharmaceutical education — 2 years of study).

– the definition of RM is not established;
– a number of bylaws of the contract system in the field of procurement establish barriers and restrictions in the procurement of RMs, which may be the basis for canceling ongoing procurements in cases where their subject is packaged RMs.

In turn, the English Rules directly indicate that a violation of the primary packaging automatically makes the medicine unregistered and the packaged RMs cease to comply with the registration certificate. A similar legal structure operates in Germany [15, 16].

Also, a feature that we consider necessary to note is the expanded right of pharmaceutical workers, provided for in section 12 of the English Rules, allowing the dispensing of prescription medicines without a doctor's prescription in the following cases:

– the doctor has confirmed (orally and (or) in writing) the patient's need for the drug, and in this case, the prescription must be provided to the pharmacy within 72 hours from the moment of dispensing the drug;
– during pharmaceutical counseling, the pharmacist came to the unambiguous conclusion that in this situation the patient cannot get a prescription for the drug, and any delay in taking the drug will lead to health risks and (or) the requested drug was prescribed to the patient earlier.

Compounding of medicines: A model of effective regulation

The analysis of the current regulatory legal documents devoted to pharmaceutical activity in the United Kingdom showed that the model of outcome-based regulation in modern pharmaceutical practice in Great Britain, in which the main emphasis is placed on achieving certain target results, and not on "strict" adherence to prescribed procedures [35–37]. Thus, there are no detailed documents in the British regulatory system that are comparable, for example, with the rules for the compounding and dispensing of drugs[22]. In other words, the regulatory acts establish a minimum level of general requirements, and not a descriptive part, in particular, a specific technology for the drug compounding.

The professional activity of pharmaceutical workers is regulated by the Pharmaceutical Council with powers in the following areas:

– creation and maintenance of a register of pharmaceutical workers, pharmacies, and their premises;
– establishment of Standards, Guidance, requirements for the implementation of professional activity of pharmaceutical workers;
– formation of educational programs for pharmaceutical workers, establishment of relevant requirements for their accreditation and continuing education;
– conducting inspections and investigations.

Mandatory and structural elements in the composition of the Pharmaceutical Council are:

– regulatory committee (combines functions similar to those for the Department of Medicines and Medical Devices Regulation and the Department of Medical Education and Personnel Policy in Healthcare of the Ministry of Health of Russia);
– inspectorate (analogous to Roszdravnadzor);
– appeals committee (appeal against orders issued by the inspectorate, there is no analogue in Russia).

The latter is an important part of the dialogue between control and supervisory bodies in any sphere of economic activity. For example, the pre-trial (out-of-court) procedure for appealing decisions and actions (inaction) of Roszdravnadzor (territorial body), as well as its officials, is regulated by paragraphs 110–132 of the order of Roszdravnadzor dated July 10, 2020 No. 5974[23], which states that complaints can be sent to the head of Roszdravnadzor or the Ministry of Health of Russia. In such an iteration, the interested person appeals the decisions of the inspectorate to it, and the higher organization (the Ministry of Health of Russia) does not have a structural unit that would perform such functions.

The Pharmaceutical Council has the right to determine independently other elements of its organizational structure, and is also obliged to consult with the professional community (existing business, expert and educational organizations, and others) before introducing any rules regulating the professional activity of pharmaceutical workers.

The Pharmaceutical Council is the main body that carries out the function of developing and implementing regulatory legal regulation of the professional activity of pharmaceutical workers. At

[22] Order of the Ministry of Health of the Russian Federation dated May 22, 2023 No. 249n "On Approval of the Rules for the compounding and Release of Medicines for Medical Use by pharmacy Organizations Licensed for pharmaceutical activities". Available from: https:// clck.ru/3MEfx2. Russian

[23] Roszdravnadzor Order No. 5974 dated July 10, 2020 "On Approval of the Administrative Regulations of the Federal Service for Healthcare Supervision on the Implementation of State Quality Control and Safety of Medical Activities. Available from: https://clck.ru/3MEfxu. Russian

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the time of this study, the Pharmaceutical Council has developed and implemented more than 20 different standards and guidelines that are mandatory for pharmaceutical workers[24] to comply with. The Standards of the Pharmaceutical Council consist of nine key principles:

1. The central role of the patient (pharmacists must put the interests of patients first, ensuring access to safe and effective pharmacotherapy).
2. Teamwork (pharmacists must cooperate with medical workers to ensure comprehensive care for patients).
3. Omnichannel communication model (doctor–patient–pharmacist).
4. Professional behavior (pharmacists must demonstrate high standards of professional behavior and ethics).
5. Professional knowledge and skills (pharmacists must maintain and develop their professional knowledge and skills).
6. Professional decisions (pharmacists must make informed decisions based on evidence and knowledge).
7. Respect and confidentiality (pharmacists must respect the rights of patients and ensure the confidentiality of their data).
8. Responsibility (pharmacists must demonstrate leadership qualities and take responsibility for their actions).
9. Risk management (pharmacists must identify and minimize risks associated with pharmaceutical practice).

The described principles are largely harmonized with the concept of providing pharmaceutical care adopted in the EU [13]. In our previous works, we have repeatedly described the European concept of providing pharmaceutical care in the form of a set of pharmaceutical services, as well as the gradual "simplification" of the concept of pharmaceutical activity, pharmacy infrastructure, pharmacy technologies, and personnel qualifications in the Russian Federation [13, 21, 38]. British law does not specify the full list of existing pharmacy services, however, the Standards of the Pharmaceutical Council for pharmacists[25], they include all services provided by pharmacies, including activities related to the retail sale of drugs, their dispensing, storage, transportation, compounding, clinical services of pharmacies (vaccination, screening, etc.), and pharmaceutical counseling. In 2022, amendments were made to the English Law, which introduced:

- definition of "Relevant Pharmacy Service" — a pharmaceutical service that is provided in MOs, nursing homes, prisons, and other social institutions;
- position of Chief Pharmacist [39, 40] — the authorized pharmacist for the provision of pharmaceutical services in the above-mentioned institutions, in the absence of a license for the retail sale of drugs.

Based on the content of the explanatory note[26], the described changes were introduced to strengthen the protection of medical workers from criminal liability in terms of providing pharmaceutical services without the presence of a pharmacy in the MO. At the same time, in Russia, against the background of the problem of the availability of medicines and pharmaceutical care, these issues have only developed due to the shortage of pharmacies and pharmaceutical workers in rural settlements in which there are no pharmacies. In particular, the solution is implemented through the retail sale of drugs through outpatient clinics, feldsher and feldsher-midwife stations, centers (departments) of general medical (family) practice (Article 55 of Federal Law-61). On the other hand, at the time of the study, a draft law was published, according to which it is proposed to expand the functionality of the Russian Post Office for the retail sale of over-the-counter drugs in remote and sparsely populated areas without obtaining a pharmaceutical license and complying with special storage conditions[27], leaving open questions about ensuring the quality of medicines, storage requirements, compliance with dispensing rules, and possible criminal liability in terms of providing pharmaceutical services, including pharmaceutical counseling.

For the purposes of this study, it is necessary to highlight the following general features from the main standards and guidelines[28, 29] of the Pharmaceutical Council:

[24] Standards and guidance for pharmacy professionals. Available from: https://clck.ru/3MDajU
[25] Standards and guidance for pharmacy professionals. Available from: https://clck.ru/3MDajU
[26] The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022. Available from: https://clck.ru/3MEVGG
[27] On amendments to certain legislative acts of the Russian Federation. Available from: https://clck.ru/3MgppC. Russian
[28] Standards for pharmacy professionals. Available from: https://clck.ru/3MDaUE
[29] Standards for registered pharmacies. Available from: https://clck.ru/3MEah7

1. Requirements for personnel:
– pharmaceutical workers are obliged to ensure the safety and quality of the services provided. If situations arise that go beyond their competence, they should seek help from other specialists;
– delegation of tasks should be carried out exclusively to qualified persons who have undergone appropriate training, with mandatory provision of the proper level of control over the performance of assigned functions;
– all employees involved in the process of compounding and dispensing of drug must have the necessary professional knowledge, skills, and experience.
2. Requirements for premises:
– must be safe, clean, properly maintained, and suitable for the pharmaceutical services provided and comply with established sanitary standards (including confidentiality requirements for clinical services).
3. Requirements for equipment. All equipment used must:
– come from trusted suppliers;
– correspond to its purpose;
– be protected from unauthorized access by third parties;
– be properly operated and maintained.
4. Documentation and registration:
– all records related to the provision of pharmaceutical services must be kept and maintained up to date, all personal information about patients must be processed in such a way as to ensure its confidentiality.
5. Obligations of the pharmacy owner:
– Pharmacy owners must ensure that all personnel are familiar with the standards and guidelines of the Pharmaceutical Council, understand the importance of their compliance, and are aware of all responsibility for their non-compliance.

Basic principles of drugs compounding in pharmacy

For the activity of pharmacies in the compounding of drugs in England, a separate guide to the compounding of drugs (hereinafter referred to as the "British Guide")[30] is provided, according to which:

– responsibility for compliance is borne by the owners of pharmacies, who are also obliged to ensure the implementation of other regulatory requirements related to the legislation on the circulation of medicines;
– deviations from the guiding principles described in the guide are permissible in cases where the achievement of established standards can be implemented in other ways and provided that the final results;
– compounding of IPPs is allowed provided that such EMs are intended for subsequent sale through pharmacies of one pharmacy (as a legal entity);
– patient can expect that the compounded drug will correspond in quality and safety to the same drug in the case of its production under a production license.

From the point of view of good practices, the British Guide distinguishes five principles that must be observed in production pharmacies:

Principle No. 1. Ensuring the safety of EMs for patients through an effective risk management system.

Each production pharmacy must develop and approve regulatory provisions that allow minimizing the risks to patients associated with the drug compounding. This principle covers the following key aspects.

1.1. Risk assessment

According to the British Guide, risk assessment means a systematic analysis of factors that can cause harm to patients or other persons, as well as the formation of necessary measures to neutralize such factors.

The risk assessment methodology must demonstrate its effectiveness for each address of pharmaceutical activity and, in particular, include provisions and procedures on:

– pharmaceutical examination of the prescription (checking, incompatibilities, doses, etc.);
– verification of the method of drug compounding;
– identification of specific risks associated with the raw materials;
– ensuring the necessary level of training and qualification of personnel;
– compliance of premises, equipment, and sanitary regime with the types of compounding nomenclature;
– preventing the risk of contamination;
– circumstances under which a re-assessment of risks will be required.

[30] Guidance for registered pharmacies preparing unlicensed medicines. Available from: https://clck.ru/3MEf3X

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1.2. Internal audit

For the purposes of ensuring compliance with safety and quality standards of EMs, it is necessary to conduct a regular audit of the processes of drugs compounding. At the same time, the frequency of the internal audit is determined by the parmacy independently, where the time intervals must be justified and reflect the specifics of the activity of each pharmacy at the address of pharmaceutical activity. The audit must include at least:

- a comprehensive inspection of premises (temperature, humidity, lighting, sanitary standards);assessment of equipment and its operating conditions;
- analysis of the processes of drug compounding and their quality control;
- assessment of the level of training and qualification of personnel;
- verification of record keeping, including in relation to the methods used for drug compounding, ensuring traceability of raw materials, proper labeling of EMs, and data storage.

The results of the audit should be used to adjust existing procedures, eliminate identified shortcomings, and improve the overall level of quality of pharmaceutical services provided.

1.3. Review of risk assessment

If there are changes in the working conditions of the pharmacy that affect the process of drug compounding, it is necessary to review the risk assessment and related procedures. Such changes may include:

- replacement of pharmaceutical workers;
- introduction of new personnel into the processes of drug compounding;
- modernization or replacement of equipment;
- change of suppliers of raw materials and packaging materials;
- registration of incidents or complaints filed by the public and the medical community;
- change of environmental conditions or technical characteristics of premises.

The review of the risk assessment must be documented and serve as the basis for conducting a new risk assessment if required.

1.4. Recall procedures

The pharmacy must have developed and validated procedures for recalling, withdrawing from circulation, and subsequent destruction of compounded drug in case of detection of factors that pose a risk to patients. Such procedures must indicate the person who is responsible for the implementation of these procedures, as well as establish appropriate procedures, including the sequence of actions and indication of supervisory authorities and (or) organizations that must be notified of the procedure for recalling, withdrawing from circulation, and subsequent destruction of EMs. The instructions must provide additional mechanisms that allow each employee of the pharmacyto report a suspicion that the drug may be substandard or unsafe.

1.5. Responsibility

For each address of pharmaceutical activity, records must be kept that allow determining which of the pharmacists is responsible for the compounding of a specific medicine, as well as which pharmaceutical technicians and other employees of the PO participated in this process (if applicable).

1.6. Record keeping

All stages of drug compounding must be documented. The duration of record keeping must be justified and determined by the pharmacy independently. At the same time, the period of their storage must be sufficient to conduct an investigation in case of incidents or complaints. The records must include information at least in relation to:

a) The process of drug compounding, including:

- description of the key stages of drug compounding;
- detailed calculations with double checking;
- date of compilation of the worksheet (standard operating procedure for drug compounding);
- surname and name of the pharmacist who preparation the drug, full name of the pharmacist who approved the release of the finished product;
- surname and name of the pharmaceutical technician who participated in the process of drug compounding (if applicable);

b) raw materials, including:

- source of receipt (compounding of drug or wholesale distributor);
- certificate of conformity (if applicable)31;
- certificate of analysis (if applicable)32;
- batch number;
- expiration date (if available);
- surname and name of the pharmacist who checked the raw materials;
- description of the packaging.

[31] A certificate of conformity confirming that the raw materials meet the established requirements or specifications, but do not contain test results.

[32] A certificate containing the results of the test results of the feedstock together with an assessment of its compliance with the declared specification.

c) compounded drug, including:
– date of compounding;
– batch number;
– expiration date;
– date of dispensing to the patient.
d) patient, including:
– surname and name;
– patient's address;
– contact details (phone, email, etc.);
– sample of the labeling that was applied to the drug;
– surname and name of the person who created the label layout.
e) prescription (in case of dispensing by prescription), including:
– surname and name of the doctor (contact details);
– patient's age;
– other prescription data.
f) incidents and complaints, including:
– reports of suspected adverse reactions;
– complaints and comments.

Principle No. 2. High professional competence and continuous education.

All employees of the pharmacy who participate in the drugs compounding must have the necessary qualifications, undergo appropriate training, and constantly improve their knowledge, skills, and abilities.

2.1. Training

Admission to the implementation of activities for the drugs compounding is granted only after mastering the corresponding level of the educational program. If an employee is in the process of training, then a mentor must be assigned to him, who will exercise proper control.

To work with EMs, the personnel of the pharmacy require knowledge and skills that go beyond the retail sale of RMs.

If an employee does not have sufficient qualifications, the owners of the pharmacymust organize additional training. Special attention should be paid to regular knowledge and skills checks, especially in situations where work is carried out with specific raw materials and (or) methods of drug compounding, including with raw materials and methods that are used in relatively rare cases.

Employees working with highly hazardous and (or) active raw materials (cytostatics, hormones, biological raw materials) [41] or in conditions requiring compliance with special sanitary measures (compounding of sterile DFs) must undergo special training corresponding to the nature of the work performed.

2.2. Training records

The owners of the pharmacy are obliged to keep records of the training of personnel and store information for as long as it is considered reasonable and justified. Such records must be available upon request from authorized bodies and organizations.

Principle No. 3. Compliance of the production environment with the nature of the work performed.

Premises intended for the drugs compounding must comply with the required level of cleanliness classes. It is required to implement all measures to prevent contamination and the risks of its occurrence.

3.1. Measures to minimize contamination

Premises intended for the drug compounding must be designed to correspond to the nature of the work performed. If there is a need, it is necessary to have separate work areas for the drug compounding of different classes. The working environment of the premises must correspond to the established cleanliness class.

Specific measures should be taken to prevent or minimize the risk of cross and microbiological contamination during the drug compounding.

The described factors must be taken into account at the stage of conducting the initial risk assessment.

3.2. Records on compliance with the sanitary regime

It is necessary to keep records on compliance with the sanitary regime, including standard operating procedures for cleaning premises and equipment, as well as assessments of microbiological purity. Records should be kept for as long as it is considered reasonable and justified.

Principle No. 4. The procedure for providing pharmaceutical services must ensure the effectiveness and safety of EMs.

4.1. Raw materials

The quality of the finished product directly depends on the quality of the raw materials. The pharmacy must ensure that it comes from trusted suppliers.

4.2. Quality Assurance

The quality control system must consist of at least the following elements:
– use of worksheets;
– confirmation of the quantity and identity of ingredients;
– availability of qualified and trained personnel;
– properly maintained equipment.

The pharmacy must guarantee the proper quality of EMs. When compounding a series of drugs, including in the form of IPPs, the quality control system must be more extensive (for example, conducting full chemical control) than in the case of a single manufacture of EMs.

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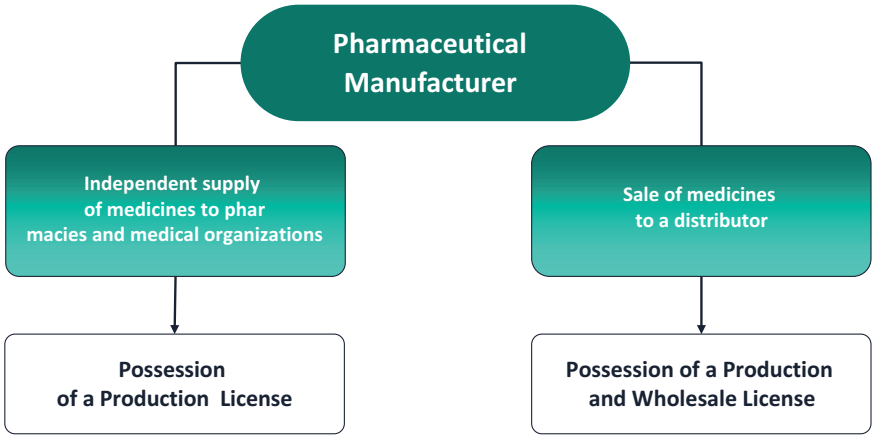

Figure 1 – Requirements for the availability of licenses for manufacturers of medicines

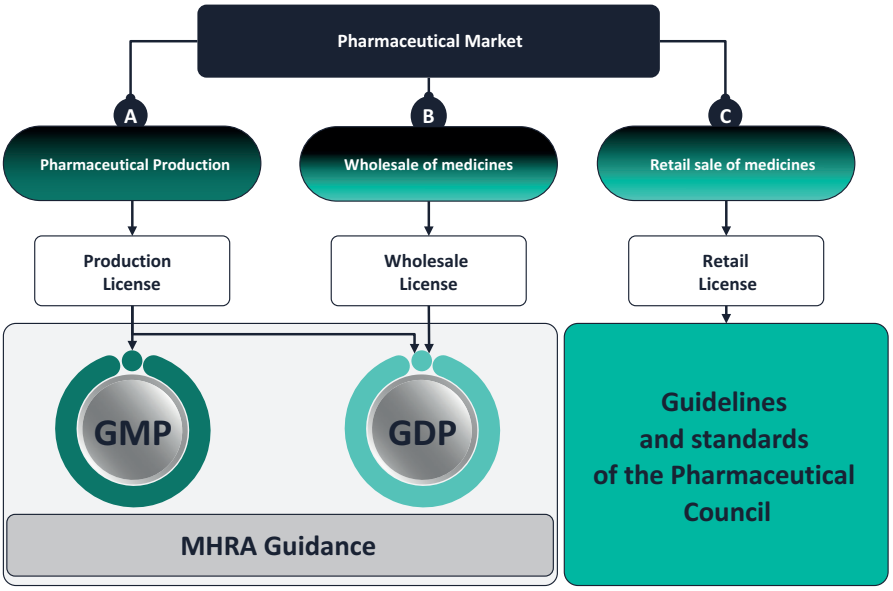

Figure 2 – Licensing requirements in the United Kingdom.

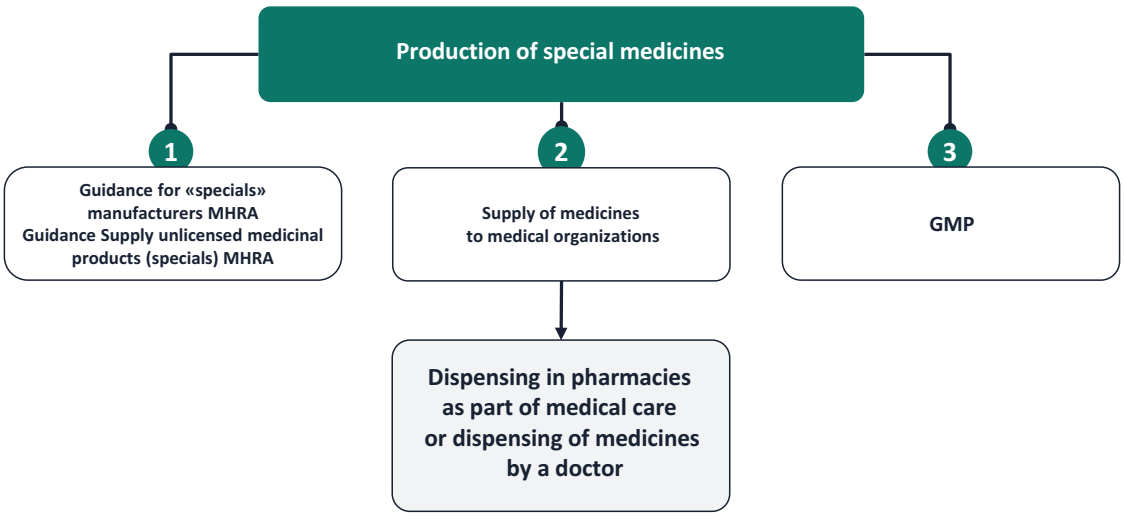

Figure 3 – Licensing requirements for special medicines.

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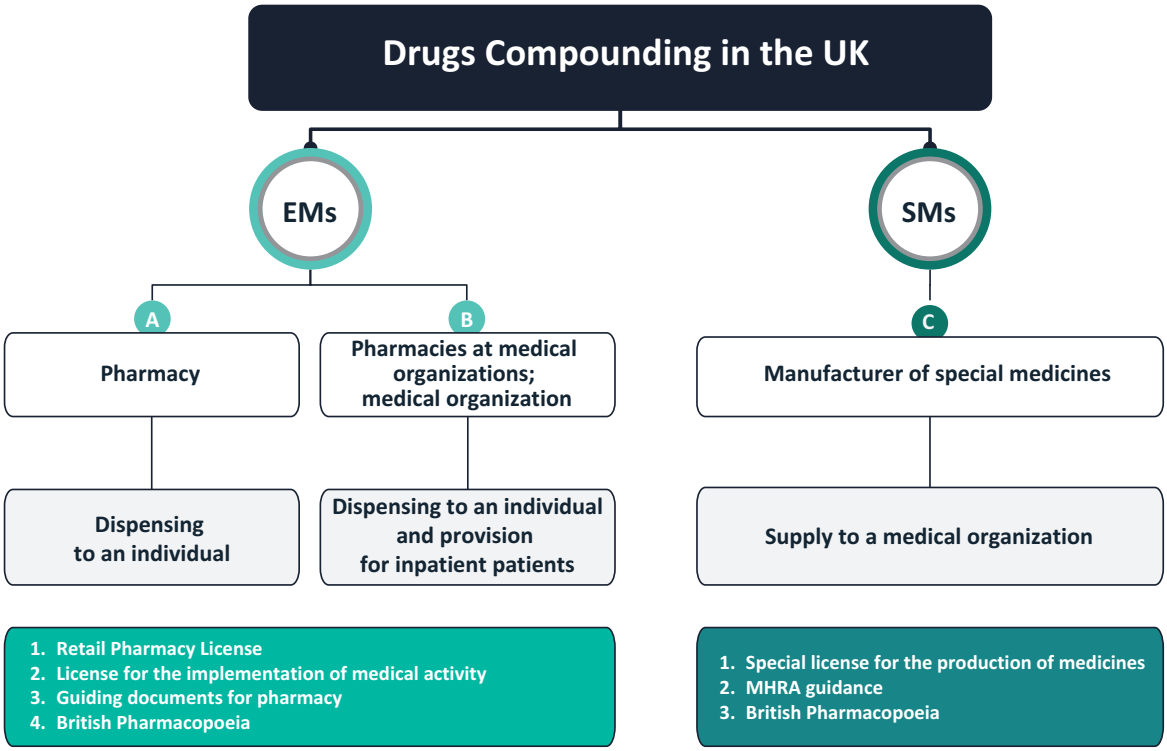

Figure 4 – Schematic diagram of organizational approaches to compounding of drugs in the UK.
Note: ELP — extemporaneous medicines; SLP — special medicines.

4.3. Information for patients

Each production pharmacy must have a patient information system, according to which the responsible pharmacist (or other competent pharmaceutical worker) informs him that he will be dispensed an unregistered drug, where, in certain cases, there is no clinical trial data and information on the safety and effectiveness of such medicine.

Principle No. 5. Compliance of equipment and premises with the nature of the work performed.

5.1. Specialized equipment and premises

The pharmacy must have equipment and premises specially designed for the purposes for which they will be used by employees. The equipment must be of high quality and accuracy (if necessary) to guarantee the compounding of high-quality and safe EMs.

5.2. Equipment maintenance logs

For each type of specialized equipment, it is necessary to keep maintenance logs, including data on: conducted verifications and calibrations; planned and unscheduled maintenance; identified malfunctions and their elimination. Records should be kept for as long as it is considered reasonable and justified.

The British Guide recommends that pharmacies additionally use the following in their activities for the drugs compounding:

- The MHRA Orange Guide to Rules and Guidance for Pharmaceutical Manufacturers and Distributors;
- PIC/S Guide to Good compounding Practice for Medicinal Products;
- Resolution on the requirements for the quality and safety of the compounding of medicines in pharmacy for the special needs of patients.

Extemporaneous compounding in the British Pharmacopoeia

The British Pharmacopoeia (hereinafter — BP)[33] contains 94 pharmacopoeial monographs on individual formulations of ELP in different dosage forms, as well as a number of general pharmacopoeial monographs (hereinafter — GPM) devoted to various aspects of drug compounding:

1. GPM “Pharmaceutical preparations” — from the European Pharmacopoeia and introducing the classification of ELP, including those made in the form of AIS [13];
2. GPM “Unlicensed Medicines”.

In contrast to other global regulatory systems that have been previously studied by the authors of this study, this GPM is devoted to both EMs and SMs (hereinafter jointly referred to as NMs), which repeatedly emphasizes the continuity of good practices. The document defines key aspects of

[33] The authors have access to the full version of the British Pharmacopoeia 2022 edition.

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quality assurance in the compound (production) of NMs, including compliance with aseptic conditions, microbiological control, shelf life, labeling and stability of drugs, and also indicates the features of dissolution and uniformity of dosage tests for oral suspensions. Particular attention is paid to the need for compliance of the active and excipient substances used with pharmacopoeial standards, as well as ensuring safety for patients through strict control over compounding processes. In particular, the GPM contains the following features:

- it is emphasized that the provisions of this article do not apply to actions for intra-pharmacy packaging of RMs;
- NMs must comply with pharmacopoeial requirements during testing, however, the use of alternative quality control methods is allowed if it is impossible to regularly apply the entire scope of full chemical control and (or) specific methods of analysis;
- each series of sterile compounded / produced NMs must be tested for sterility, if the shelf life of the NMs is less than 90 days, the analysis is carried out retrospectively and is part of the control in the compounded / produced process;
- in the case of individually compounded / produced NMs, the batch size is equal to one package, under these circumstances, one package of NMs compounded (produced) during one work shift is subjected to a sterility test (continuous period of work with the participation of the same employees34, under the same environmental conditions, using the same equipment and materials). If no series of NMs has been compounded (produced) during one work shift, then control samples (English Dummy samples) must be provided;
- sterility tests may not be carried out in the case of validation of the compounding (production) process of NMs.

3. The appendix of the fifth volume of the BP contains an additional chapter devoted to NMs, also entitled “Unlicensed Medicines” (NMs Guide). It emphasizes that this type of drug therapy plays an important role in modern medical practice, while such drugs require special attention from doctors, pharmaceutical workers and their compounding / produced.

The document states that, as a rule, owners of a special license for the production of medicines also have a retail pharmaceutical license and, in fact, carry out two types of activities on the basis of a joint-stock company. The MHRA guidance for manufacturers of SMs refers to the same fact. The described practice is not unique to the UK. As noted above, a similar model is implemented in the USA — with 503A [42–44] and 503B pharmacies, and in the EU [45–47] — the mentioned model echoes the European resolution [48, 49][35], according to which GMP rules[36] are recommended to be used as a reference when compounding the “high-risk drugs” group, and the PIC/S Guide[37] to Good compounding Practice for Medicinal Products — when compounding “low-risk drugs”.

In addition, additional chapters cover issues related to:

- the use of NMs without preservatives, especially in pediatric and neonatal practice;
- bioequivalence of oral liquids, especially in the case of drugs with a narrow therapeutic index, since data on the bioavailability of NMs are usually absent, there is a risk of mismatch between clinically significant indicators of the concentration of the active substance in the blood and the prescribed dosage of the drug, and therefore it is recommended in some cases to carry out the necessary clinical monitoring;
- stability of NMs, which is assessed taking into account an extensive list of factors listed in the BP that affect the shelf life of compounding (produced) products. Some PMs devoted to specific NMs formulations provide recommended shelf lives. However, the final value of the shelf life is established by the persons responsible for the compounding or production of drugs.

Within the NMs Guide, a special subsection is dedicated to standards for aseptic compounding (production) of drugs. The following key features of the document should be highlighted:

1. It is emphasized that a special license for the production of medicines appeared in the British regulatory system as a logical development of the activity of dilution (reconstitution) of medicines, which is directly related to the need to minimize the risk of microbiological contamination, ensure accurate dosing and the possibility of full documentary support of the entire

[34] The qualifications of employees depend on the type of license.

[35] Committee of Ministers, Council of Europe. Resolution CM/Res (2016) 1 on Quality and Safety Assurance Requirements for Medicinal Products Prepared in Pharmacies for the Special Needs of Patients, 2016.

[36] Scheme P.I.C. Guide to good manufacturing practice for medicinal products annexes, 2009.

[37] Scheme P.I.C. PIC/S guide to good practices for the preparation of medicinal products in healthcare establishments. PE 010i; 2014.

compounding process (production of medicines).

2. In aseptic premises (English Aseptic Units; aseptic unit) a wide range of drugs are manufactured / produced (parenteral nutrition solutions, cytostatics, radiopharmaceuticals, etc. It is separately emphasized that the implementation of activities for dilution (reconstitution) of drugs is pharmacoeconomically beneficial.
3. The subsection emphasizes the need to implement a comprehensive quality assurance system covering all stages of the drug's life cycle – from the purchase of raw materials to the storage and supply of finished products. Such a system should include standard operating procedures, regular monitoring of the environment and finished products, process validation, training and certification of personnel, internal and external audits, etc.
4. Any manipulations with cytostatic drugs should be carried out in biological safety cabinets of type II or in a pharmaceutical isolator, including operations of dilution (reconstitution) of toxic drugs.

In the subsection of this work devoted to the Pharmaceutical Council, it was noted above that it is obliged to consult with the professional community (existing business, expert and educational organizations, etc.) before introducing any rules regulating the professional activities of pharmaceutical workers. The regulatory documents of the Pharmaceutical Council, as well as the BP, directly refer to the guidelines of the Royal Pharmaceutical Society (RPS)[38], which has been continuously operating since 1841. Thus, the aforementioned subsection of the BP, devoted to standards for aseptic compounding (production) of drugs, recommends organizing activities for the compounding of drugs (without a special license for the production of drugs) in accordance with the RPS Guide[39] "Ensuring the quality of services for aseptic preparation of medicines", which in its content is similar to chapter 797 of the US Pharmacopoeia (USP)[40]. The UK Guidance, as well as the NHS Standard for ensuring aseptic preparation of drugs in hospital pharmacies[41], refers to it. There are other NGOs in Britain that issue similar documents that are taken into account in the professional activities of joint-stock companies and medical organizations, but RPS is undoubtedly the leading one.

In general, the entire set of standards, guidelines and other regulatory legal documents studied in the course of this work, devoted to the features and directly the processes of drug compounding, is based on the basic principles of good practices, which are highly comparable with chapters 795, 797 and 800 USP, as well as with the PIC/S Guide to Good compounding Practice for Medicinal Products, which was discussed in detail in the corresponding monograph [13] and individual scientific publications [15, 16].

The final scheme of organizational approaches to drug compounding in the United Kingdom is presented in Figure 4.

Study Limitations

Only the full version of the BP 2022 edition was available to the authors of the study, while the online version of the British Pharmacopoeia (in the 2026 edition), containing current updates and additions, is not available for free access and requires a special subscription.

CONCLUSION

Despite the fact that there is a special license for the production of medicines, under this type of activity, it is undoubtedly worth understanding precisely the pharmacy compounding of drugs, which is confirmed both by the current practice of Great Britain and by the analysis of the regulatory legal framework. This mechanism is distinguished by analogy with the approach to the activities of 503B pharmacies in the United States. The authors of the work failed to find separate guidelines specifically developed for compounding of drugs by medical organizations without a pharmaceutical license, but the analysis allows us to conclude that the same standards, methods and norms are used in such activities as are applied to joint-stock companies. Thus, we can talk about the formation of a unified system of regulatory support for drug compounding activities, including elements of regulation of both the European Union and the United States, as well as the introduction of "adapted" GMP requirements into the practice of pharmacy drug compounding. Such a regulatory structure indicates cross-border unification of approaches and harmonization of requirements for the quality and safety of EMs.

The described unification of regulatory requirements emphasizes the increasing role of pharmacy drug compounding in the modern healthcare system, which is directly related to the expansion of the

[38] So L. About the royal pharmaceutical society; 2014.
[39] Quality Assurance of Aseptic Preparation Services: Standards. Available from: https://clck.ru/3Mc5pY
[40] USP-NF/PF online. Available from: https://clck.ru/3MkGLp
[41] Assurance of aseptic preparation of medicines. Available from: https://clck.ru/3Mc68g

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functions of joint-stock companies in providing patients with personalized drugs. All the approaches considered in this study and in the previous works of the authors demonstrate a steady trend towards the fact that the activities of joint-stock companies are becoming a key link in providing patients with personalized drugs of all types of therapy, which seems to be a logical and appropriate direction for the development of pharmaceutical activities, which contributes to a more flexible and responsible provision of special medical needs of patients.

Such an expansion of the functionality of joint-stock companies is impossible without the corresponding development of the concept of pharmaceutical care as a systemic element of healthcare, which is confirmed by the practice of countries with a developed regulatory system. As the results of the study showed, pharmaceutical workers are able to make a significant contribution to the accessibility and quality of medical and social care to the population through the development of the concept of providing pharmaceutical care, in the development of which it is necessary to consider the issues of citizens' access to the necessary drugs in a comprehensive manner. The British healthcare regulatory system has separate legislative documents that define the foundations in the field of organization of pharmaceutical affairs, the functioning of joint-stock companies, the provision of pharmaceutical care by them and the provision of pharmaceutical services in a wide range of competencies.

In these circumstances, the lag of the Russian regulatory legal framework in the regulation of pharmacy drug compounding looks especially noticeable, which confirms the need for systemic changes. This study has once again demonstrated that the current state of legal regulation of drug compounding activities in Russia needs to be improved in terms of the circulation of Ems and packaged RMs, which is not sufficiently regulated by current legislation and should be harmonized with international norms.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS' CONTRIBUTION

Devi D. Mamedov — analysis of normative and legal information, search and collection of literary sources, writing and editing the text of the manuscript; Dmitry S. Yurochkin — analysis of normative and legal information, search and collection of literary sources, writing and editing the text of the manuscript; Svetlana N. Egorova — analysis of normative and legal information, search and collection of literary sources, writing and editing the text of the manuscript; Zakhar M. Golant — analysis of normative and legal information, search and collection of literary sources, writing and editing the text of the manuscript; Igor A. Narkevich — analysis of regulatory and legal information, search and collection of literary sources, writing and editing of the manuscript text. All authors confirm that their authorship meets the international ICMJE criteria (all authors have made significant contributions to the development of the concept, research and preparation of the article, read and approved the final version before publication). All authors made an equivalent and equal contribution to the preparation of the publication. All authors confirm that their authorship meets the international ICMJE criteria (all authors made a significant contribution to the development of the concept and preparation of the article, read and approved the final version before publication).

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