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Problems and Solutions of Pharmaceutical Packaging in Bulk

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To date, pharmaceutical activities in the manufacture of medicines in a pharmacy, intra-pharmacy packaging of registered medicines in Russia and the countries of the Eurasian Economic Union (EAEU), is one of the priorities of regulatory authorities in order to improve drug supply.

The aim. To study the current state of legal regulation of the circulation of medicines "in bulk" and the possibility of their packaging in a pharmacy.

Materials and methods. To solve the tasks set, the methodology of system analysis in the field of drug provision, content analysis of documents regulating the sphere of circulation of drugs was used. The regulatory framework of the study was the legislative and by-laws regulating the sphere of circulation of medicines of the Russian Federation and the common market of the EAEU. The search for regulatory legal acts was carried out in the Directory of the legal system "ConsultantPlus". In the course of the research, a set of scientific methods was used such a systematic, logical, structural and comparative.

Results. The article consider the issues of legal regulation of the circulation of medicines "in bulk" in the pharmaceutical market. The current state of the legislative and regulatory framework has been studied and the problems of legal regulation of packaging of medicicnes "in bulk" in pharmacies have been identified. The article also focuses on the general problem of compliance with modern packaging requirements for medicines compounded in pharmacy. The possibility of introducing a new concept of "Pharmacy packaging" into Federal Law No. 61-FZ dated April 12, 2010 "On the circulation of medicines" is considered. The approaches developed in world practice to the regulation of issues related to the packaging of drugs "in bulk" in pharmacy are considered. Based on the results of the study, the possibilities have been identified and ways to improve the mechanisms of state regulation have been proposed.

Conclusion. Packaging of medicines "in bulk" will increase the effectiveness of individual drug therapy, optimize and reduce the cost of circulation of budget funds, pharmacies and citizens.

Keywords: drugs manufacturing; extemporaneous drugs; "in bulk" medicines; packaging; pharmacy; drug supply; drug packaging.

Abbreviations: EAEU — Eurasian Economic Union; SRMs — State Register of Medicines; GM — general monograph; SPh — State Pharmacopoeia; EEC — Eurasian Economic Commission; IS MMM — Information System for Monitoring the Movement of Medicines; EDs — extemporaneous drugs; PPD — prescription and production department; SEZ — special economic zone.

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Расфасовка лекарственных препаратов «in bulk» в аптечной организации: проблемы и решения

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На сегодняшний день фармацевтическая деятельность в части изготовления лекарственных препаратов (ЛП) в аптечной организации (АО), внутриаптечной фасовки зарегистрированных ЛП в России и странах Евразийского экономического союза (ЕАЭС), является одной из приоритетных задач регуляторных органов в целях улучшения лекарственного обеспечения.

Цель. Изучить современное состояние правового регулирования обращения лекарственных препаратов «in bulk» и возможность их расфасовки в аптечной организации.

Материалы и методы. Для решения поставленных задач использована методология системного анализа в области лекарственного обеспечения, контент-анализ нормативных документов, регулирующих сферу обращения лекарственных средств (ЛС). Нормативной базой исследования выступали законодательные и подзаконные акты, регулирующие сферу обращения ЛС Российской Федерации и общего рынка ЛС ЕАЭС. Поиск нормативных правовых актов осуществлялся в Справочнике правовой системы «КонсультантПлюс». В ходе исследования применялся комплекс научных методов: системный, логический, структурный и сравнительный.

Результаты. В статье рассматриваются вопросы правового регулирования обращения ЛП «in bulk» на фармацевтическом рынке. Изучено современное состояние законодательной нормативной базы и определены проблемы правового регулирования расфасовки ЛП «in bulk» в АО. Также в работе уделено внимание общей проблеме соответствия современным требованиям к упаковке для ЛП, изготовленных в АО. Рассмотрена возможность введения нового понятия «Аптечная упаковка» в Федеральный закон от 12.04.2010 г. № 61-ФЗ «Об обращении лекарственных средств». Рассмотрены сложившиеся в мировой практике подходы к регулированию вопросов, связанных с расфасовкой ЛП «in bulk» в АО. По результатам исследования определены возможности и предложены пути совершенствования механизмов государственного регулирования.

Заключение. Расфасовка ЛП «in bulk» позволит повысить эффективность индивидуальной лекарственной терапии, оптимизировать и снизить издержки обращения средств бюджета, АО и граждан.

Ключевые слова: изготовление лекарственных препаратов; экстемпорльные лекарственные препараты; лекарственные препараты «in bulk»; расфасовка; аптечная организация; лекарственное обеспечение; упаковка лекарственных препаратов.

Список сокращений: ЛП — лекарственный препарат; АО — аптечная организация; ЕАЭС — Евразийский экономический союз; ЛС — лекарственное средство; ГРЛС — Государственный реестр лекарственных средств; ОФС — общая фармакопейная статья; ГФ — Государственная фармакопея; ЕЭК — Евразийская экономическая комиссия; ИС МДЛП — информационная система мониторинга движения лекарственных препаратов; ЭЛП — экстемпоральные лекарственные препараты; РПО — рецептурно-производственный отдел; ОЭЗ — особая экономическая зона.

INTRODUCTION

Improving the accessibility of medicines is a key task for regulatory bodies in fulfilling constitutional obligations for providing medicines to the population[1] [1–3].

Since September 2023, changes enshrined in Federal Law No. 502-FZ[2] of December 5, 2022 in Article 56 of Federal Law No. 61-FZ[3] of April 12, 2010 regarding the compounding and dispensing of medicines in a pharmacy have come into force in the Russian Federation. A significant legislative addition has been made to Part 2 of this article, allowing the use of medicines included in the State Register of Medicines for Medical Use (SRMs) when compounding medicines for medical use in a pharmacy. Subsequent improvement of this legislative norm is defined by the amendments introduced by Federal Law No. 1-FZ[4] of January 30, 2024, establishing the possibility of using both medicines registered under the national system and those registered in the common market of medicines of the EAEU and, accordingly, included in the unified EAEU[5] during manufacturing. This innovation significantly expands the possibilities of using medicines in circulation in the common EAEU market, which determines the particular relevance of sanctions restrictions in modern conditions.

General Pharmacopoeia Monograph (GM) GM.1.1.0004. Sampling[6] of the State Pharmacopoeia (SPh) of the Russian Federation XV edition defines the concept of "unpackaged products (bulk)" as a medicine in large packaging, including in an established dosage form, that has passed all stages of the technological process, except for packaging, and is intended for subsequent dispensing or production of medicines.

Therefore, in accordance with the new version of Article 56 of Federal Law No. 61-FZ of April 12, 2010, pharmacies have the right to use medicines "in bulk" and engage in their dispensing when compounding medicines.

Based on the results of the study, we proposed the introduction of a new concept of "Pharmacy dispensing and Packaging" into the legislative framework of the sphere of circulation of medicines, and considered solutions to emerging topical issues [4–6].

Timely organisation of medicine provision requires a comprehensive systematic approach to legal regulation, ensuring the procedure for its provision [7–9]. Dispensing of medicines "in bulk" will be of great importance for increasing personalized medicine and value-based healthcare provision to the country's population [10–12].

THE AIM. To study the current state of legal regulation of medicines "in bulk" and the possibility of their dispensing in a pharmacy.

MATERIALS AND METHODS

The legal basis of the study included legislative and regulatory acts of the Russian Federation in the field of healthcare and circulation of medicines, the common market of medicines of the EAEU, the methodology of system analysis in the field of medicine provision, and the organization of procurement of medicines using empirical, theoretical, and quantitative methods. The empirical base was collected from the official website of the Ministry of Health of Russia, the Federal Center for Pricing and Regulation of Medicines, and the ConsultantPlus legal (reference system on a contractual basis with Sechenov University).

The information base of the study for data collection and analysis used the results of scientific articles was carried out by the authors in the scientific electronic library elibrary.ru and Google Scholar. The search was conducted using the following keywords in Russian and English: "аптечная организация", "компаудинг", "расфасовка лекарственных препаратов", "экстемпоральное производство", "in bulk", "регулирование обращения лекарственных средств", "pharmacy", "compounding", "drugs packaging", "extemporaneous compounding", "regulation of the circulation of medicines". The analysis period was from January to December 2024.

RESULTS AND DISCUSSION

An analysis of foreign practice of "in bulk" packaging revealed that in many countries, medicines "in bulk" (mainly tablets and capsules) are supplied to pharmacies in large containers in quantities of up to 1000 pieces. Upon prescription dispensing, the pharmaceutical worker places the measured number of tablets or capsules in an individual container, provides the buyer with the necessary information about the medicine, and certifies it with a personal signature [13–15].

In the USA, medicines "in bulk" are used in the manufacture of dosage forms, according to the 503B

[1] Article 41 of the Constitution of the Russian Federation (accepted by popular vote dated December 12, 1993 with amendments approved during the nationwide vote dated July 1, 2020). Russian

[2] Federal Law No. 502-FZ dated December 5, 2022 "On Amendments to art. 56 of the Federal Law "On the Circulation of Medicines". Russian

[3] Federal Law No. 61-FZ dated April 10, 2010 "On the Circulation of Medicines". Russian

[4] Federal Law No. 1-FZ dated January 30, 2024 "On Amendments to the Federal Law "On the Circulation of Medicines" and Articles 1 and [4] of the Federal Law "On Amendments to the Federal Law "On the Circulation of Medicines" and the Federal Law "On Amendments to the Federal Law "On the Circulation of Medicines". Russian

[5] The Unified Register of Registered Medicines of the Eurasian Economic Union. Available from: https://portal.eaeunion.org/sites/commonprocesses/ru-ru/Pages/DrugRegistrationDetails.aspx

[6] GM.1.1.0004. Sampling. The State Pharmacopoeia of the Russian Federation XV edition. Available from: https://pharmacopoeia.regmed.ru/pharmacopoeia/izdanie-15/1/1-1/otbor-prob/. Russian

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Bulk Drug Substances List[7], approved by the U.S. Food and Drug Administration (FDA) [16].

In European countries and in Russia, at present, the procedure for dispensing medicines in secondary or primary packaging is provided[8] [17–19].

Regulation of the packaging of medicines "in bulk" is a topical issue and requires a serious study of the existing legal framework in the field of circulation of extemporaneous drugs (EDs) [20–22], as well as the introduction of possible additions and developments in regulatory legal documents. Table 1 shows the terms and definitions relating to medicines "in bulk" and unpackaged products, prescribed in the Decision of the Eurasian Economic Commission (EEC) No. 100 of August 11, 2020[9], at the national level in GM.1.1.0004, approved by Order of the Ministry of Health of Russia No. 377 of July 20, 2023[10] and Order of the Ministry of Industry and Trade of Russia No. 916 of June 14, 2013[11].

Consequently, the current terminology indicates the harmonization of the national definition of "in bulk" products in accordance with the pharmacopoeial requirements of the common market of medicines of the EAEU.

Based on these definitions, the production of medicines "in bulk" can be carried out by one entity in the sphere of circulation of medicines — in unpackaged form, it can transfer it to another entity, including a pharmacy.

In accordance with the Regulations on the import of drugs into the customs territory of the EAEU, approved by the Decision of board of the EEC No. 30 of April 21, 2015[12] and the On the Rules for registration and examination of medicines for medical use, approved by the Decision of council of the EEC No. 78 dated November 3, 2016[13], the import of drugs is carried out on the basis of information provided in the Union Register of medicinal products. By the decision of the EEC, amendments have been made to the form of the registration certificate allowing manufacturers of drugs to indicate the form "in bulk" among the packaging options. The change allows pharmaceutical companies operating in the Union territory on an incomplete production cycle to import drugs "in bulk" for their subsequent packaging. The innovation allows confirming the drug status "in bulk" at customs and maintaining the preferential 10% VAT rate, which positively affects the pricing process of medicines compounded in pharmacies.

Information about drugs registered in "in bulk" packaging is available in the SRMs in open access on the website of the Ministry of Health of Russia[14].

In pursuance of Article 67 of Federal Law No. 61-FZ of April 12, 2010 and Decree of the Government of the Russian Federation No. 1556 of December 14, 2018[15], marking of medicines and submission of information to the Unified Federal Information System for Monitoring the Movement of Medicinal Products (MDLP) from the manufacturer to the end consumer is mandatory for all entities in the circulation of medicines [23–25]. Due to the absence of consumer dispensing on medicines "in bulk", identification means are not applied when they are imported into Russia. Marking is carried out at the company's production site during the packaging stage. Also, an exception for handling with the corresponding identification marks, in accordance with Part 1 of Article 46 "Marking of medicinal products", are medicines compounded in pharmacies.

A pharmacy that has a license for pharmaceutical activity, in accordance with Part 2 of Article 56 of Federal Law No. 61-FZ of April 12, 2010 and on the basis of Order of the Ministry of Health of Russia No. 249n of May 22, 2023, has the right to use registered finished medicines "in bulk" when manufacturing medicines. Consequently, in accordance with paragraph 54 of Chapter IV "Features of manufacturing medicines from finished medicinal products" of Order of the Ministry of Health of the Russian Federation No. 249n of May 22, 2023, it is allowed to manufacture powders from medicines "in bulk" according to the composition of the manufactured medicines and excipient (if necessary) indicated by the doctor in the prescription or requirement of the medical organization. It is not allowed to use dosage forms (tablets, capsules) of prolonged action and coated with an enteric coating when manufacturing powders. It is also not allowed to use drugs in the preparation of solutions for parenteral administration.

[7] U.S. Food and Drug Administration. 503B Bulk Drug Substances List. Available from: https://www.fda.gov/ drugs/human-drug-compounding/503b-bulk-drug-substances-list

[8] Order of the Ministry of Health of the Russian Federation dated November 24, 2021 No. 1093n "On Approval of the Rules for the Release of Medicines for Medical Use by Pharmacy Organizations, individual Entrepreneurs Licensed to carry out Pharmaceutical Activities, medical Organizations Licensed to Carry out Pharmaceutical Activities, and their Separate Units (outpatient clinics, paramedic and midwifery centers, centers (departments) of general medical (family) practice), located in rural settlements where there are no pharmacy organizations, as well as the Rules for the release of narcotic drugs and psychotropic substances registered in...". Russian

[9] Decision of the Eurasian Economic Commission dated August 11, 2020 No. 100 "On the Pharmacopoeia of the Eurasian Economic Union".

[10] Order of the Ministry of Health of the Russian Federation dated July 20, 2023 No. 377 "On Approval of General Pharmacopoeial Articles and Pharmacopoeial Articles". Russian

[11] Order of the Ministry of Industry and Trade of the Russian Federation dated June 14, 2013 No. 916 "On Approval of the Rules of Good Manufacturing Practice". Russian

[12] Decision of board of the Eurasian Economic Commission of April 21, 2015 No. 30 "About measures of non-tariff regulation".

[13] Decision of Council of the Eurasian Economic Commission No. 78 dated November 3, 2016 "On the Rules for registration and examination of medicines for medical use".

[14] State Register of Medicines of Russian Federation. Available from: https://grls.minzdrav.gov.ru/Default.aspx

[15] Order of the Ministry of Industry and Trade of the Russian Federation dated June 14, 2013 No. 916 "On Approval of the Rules of Good Manufacturing Practice". Russian

Table 1 – Terms and definitions of "medicines "in bulk"

Term and definition	Regulatory legal act
Unpackaged products ("angro", "in bulk") — a medicine in large packaging, including in a specific dosage form, that has passed all stages of the technological process, except for dispensing, and is intended for subsequent packaging or production of medicines.	Decision of the Board of the Eurasian Economic Commission No. 100 of August 11, 2020 (as amended on October 25, 2022) «On the Pharmacopoeia of the Eurasian Economic Union».
Unpackaged products ("angro") — a medicine in large packaging, including in a specific dosage form, that has passed all stages of the technological process, except for dispensing, and is intended for subsequent packaging or production of medicines.	GM.1.1.0004. Sampling of the State Pharmacopoeia of the Russian Federation XV edition.
Unpackaged products — any product that has passed all stages of the technological process except for consumer dispensing.	Order of the Ministry of Industry and Trade of the Russian Federation No. 916 of June 14, 2013 (as amended on December 18, 2015) "On approval of the Rules of Good Manufacturing Practice".

Since March 1, 2022, on the basis of Order of the Ministry of Health of Russia No. 1093n of November 24, 2021[16], it is allowed to violate (divide) the secondary (consumer) packaging when dispensing medicines, and the Ministry of Health of Russia in the corresponding letter No. 25-4/I/2-2643 of February 18, 2022[17] provides the necessary clarifications on emerging issues. In this regard, it is possible to amend paragraph 54 of Chapter IV «Specifics of manufacturing medicines from already produced ones" of the Order of the Ministry of Health of Russia No. 249n dated May 22, 2023, as follows: "...it is allowed to dispense medicines in the form of "in bulk", including according to prescriptions from doctors and requirements of medical organizations."

Thus, the introduced amendment updates the solution of regulatory issues and requirements for the corresponding consumer packaging to maintain the effectiveness and safety of dispensed and opened medicines "in bulk".

The revival and the development of medicine manufacturing in pharmaceutical organizations solve the problem of packaging according to modern trends [26–28]. It should be noted that "in bulk" medicines and medicines compounded in pharmacies are an exception to the inclusion of their data in the MDLP, which deprives the end consumer of the opportunity to verify the authenticity of the medicine online using the "Honest Sign" state labeling application. In this regard, along with quality control of compounded medications [29–31], approved by Order of the Ministry of Health of Russia No. 249n dated May 22, 2023 (section V), the most important factor in their effectiveness and safety is solving the issue of "correct" dispensing of all medicines compounded in pharmacies. It is also necessary to note that the primary packaging determines the route of administration of EDs into the patient's body, thereby ensuring the individual variability of the provided drug therapy.

In this regard, as we consider, it is possible to introduce a new concept in Article 4 of the Federal Law No. 61-FZ of April 12, 2010 "Pharmaceutical dispensing": "Pharmaceutical dispensing is a means or complex of means that ensure the quality of medicines compounded in a pharmacy, as well as ensure the process of transportation, storage, dispensing, and ergonomic use of these medicines by the end consumer."

In pursuance of the legislative innovation, it is possible to develop and approve an order of the Ministry of Health of Russia "On approval of requirements for packaging and completeness of medicines for medical use manufactured in a pharmacy". The document should take into account the requirements of section 2.4.2. "Packaging" of the Eurasian Pharmacopoeia[18], GM.1.1.0035. Packaging of Medicinal Products of the State Pharmacopoeia of the Russian Federation XV edition[19].

The new GM.1.1.0035, approved to replace GM.1.1.0025.18[20], regarding the dispensing of pharmaceutical medicines, contains information only about its compliance with the rules for the manufacture and dispensing of, approved by the authorized federal executive body.

The rules for the production of medicines in pharmacy determine the physical and chemical

[16] Order of the Ministry of Health of the Russian Federation dated November 24, 2021 No. 1093n "On Approval of the Rules for the Release of Medicines for Medical Use by Pharmacy Organizations, individual Entrepreneurs Licensed to carry out Pharmaceutical Activities, medical Organizations Licensed to Carry out Pharmaceutical Activities, and their Separate Units (outpatient clinics, paramedic and midwifery centers, centers (departments) of general medical (family) practice), located in rural settlements where there are no pharmacy organizations, as well as the Rules for the release of narcotic drugs and psychotropic substances registered in...". Russian

[17] Letter of the Ministry of Health of the Russian Federation dated February 18, 2022 No. 25-4/I/2-2643 "On the sale of medicines". Russian

[18] Decision No. 100 dated August 11, 2020 of the Board of the Eurasian Economic Commission, "On the Pharmacopoeia of the Eurasian Economic Union".

[19] GM.1.1.0035. Packaging of medicines. The State Pharmacopoeia of the Russian Federation XV edition. Available from: https://pharmacopoeia.regmed.ru/ pharmacopoeia/izdanie-15/1/1-1/upakovka-lekarstvennykh-sredstv/. Russian

[20] GM.1.1.0025.18. Packaging, labeling and transportation of medicines. The State Pharmacopoeia of the Russian Federation of the XIV edition. Available from: https://pharmacopoeia.regmed.ru/pharmacopoeia/izdanie-14/1/1-1/ upakovka-markirovka-i-transportirovanie-lekarstvennykh-sredstv/. Russian

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properties of the active and auxiliary substances of EDs in accordance with the provisions of the Order of the Ministry of Health of the Russian Federation No. 249n dated May 22, 2023, and a number of new GPMs put into effect from September 1, 2023, approved by Orders of the Ministry of Health No. 377 dated July 20, 2023, and No. 448 dated August 25, 2023[21]. Order of the Ministry of Health of Russia No. 249n dated May 22, 2023, also defines the rules for labeling pharmaceutical medicines.

For scaling up the technological process of manufacturing medicines, the primary task is to approve the formulations of medicines compounded in pharmacies. Currently, there is a collection of unified drug formulations approved by Order of the Ministry of Health of the USSR No. 223 dated August 12, 1991[22]. Consequently, the analysis and updating of extemporaneous prescriptions have not been carried out for more than 30 years. Unification and approval of modern drug formulations will serve as an important basis for resolving the issue of appropriate consumer dispensing for pharmaceutical medicines and providing the quality of the therapy.

For the proper selection of packaging materials, dispensing / closure system, including closures and other packaging elements for a specific compounded medication, one should consider the GM put into effect on May 20, 2024, by Order of the Ministry of Health of Russia No. 223 dated May 6, 2024[23], GM.1.8.0008. Stability and expiration date of Pharmacy-Made Medicinal Products[24]. In addition to the packaging requirements, the use of modern dispensing materials should also consider the GM section "Packaging, Packaging Materials and Methods of Their Analysis (subsection 1.1.2)", approved by Order of the Ministry of Health of Russia No. 377 dated July 20, 2023.

Today, one of the weak points of the pharmaceutical industry and compounding pharmacies is the dependence on imported and manufactured in Russia dispensing materials [32–34]. The state provides customs preferences, tax benefits, including effective administration, to support companies located in a special economic zone (SEZ), which certainly allows manufacturers to reduce the cost of production and significantly reduce the time to resolve organizational and administrative issues. Thus, the company "Technopolis "Moscow"" (resident (SEZ) until the end of 2024 plans to open a modern production complex for the manufacture of dispensing materials. The company's management promises to provide its products to up to 50% of Russian pharmaceutical manufacturers and access to the pharmaceutical markets of the EAEU countries. The new product line includes tubes for gels and ointments, foil for blisters, instructions for medicines, which is especially relevant for pharmacy manufacturing[25]. It should be noted that medicines compounded in pharmacies are often dispensed in glass jars, and the capacity of the packaging can be many times greater than the weight of the dosage form itself. A logical consequence in the context of political and economic sanctions [35–37] would be to consider the possibility of including the production of packaging materials for medicines in the action plan for the implementation of the program "Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030" ("Pharma – 2030")[26].

Regarding the dispensing of packaged "in bulk" medicines, in our opinion, it would be the right professional decision to pack tablets and capsules in blisters, and then in secondary dispensing in accordance with the requirements of Chapter VII "Rules for dispensing and labeling medicines" of the Order of the Ministry of Health of Russia No. 249n dated May 22, 2023. There are a sufficient number of offers on the market for presses for welding blisters of domestic production, which have a low cost and quick changeability in the process of reconfiguring to another type of blister[27].

So, appropriate quality packaging can also solve the following important issue of increasing the expiration date of dispensed medicines from "in bulk" medicinal products. In accordance with the Order of the Ministry of Health of the Russian Federation No. 249n dated May 22, 2023, the new dosage form will have a very short expiration date — no more than 14 days, while non-sterile hard gelatin capsules manufactured in pharmacies have an expiration date of 45 days. Paragraph 84 of this order allows pharmacies to establish other expiration dates for Eds they comply with the GM or it will be necessary to amend paragraph 83 of Chapter VI "Expiration date of compounded medicines". In accordance with GM.1.8.0008, the expiration date of medicines compounded in pharmacies cannot exceed 90 days.

[21] Order of the Ministry of Health of the Russian Federation No. 448 dated August 25,2023 "On Approval of General Pharmacopoeial Articles and Pharmacopoeial Articles and Amendments to Order of the Ministry of Health of the Russian Federation No. 377 dated July 20, 2023 "On Approval of General Pharmacopoeial Articles and Pharmacopoeial Articles". Russian

[22] Order of the Ministry of Health of the USSR dated August 12, 1991 No. 223 "On approval of the Collection of Unified Medicinal Prescriptions". Russian

[23] Order of the Ministry of Health of the Russian Federation dated 05/06/2024 No. 223 "On Approval of the General Pharmacopoeial Article and Amendments to the Order of the Ministry of Health of the Russian Federation dated 03/13/2024 No. 120 "On Approval of General Pharmacopoeial Articles and Pharmacopoeial Articles". Russian

[24] Ibid.

[25] By 2024, Moscow will be able to provide half of Russia with packaging for medicines. PHARMEDPROM. Available from: https://pharmmedprom.ru/news/v-2024-godu-moskva-smozhet-obespechit-upakovkoi-dlya-lekarstv-pol-rossii/. Russian

[26] Decree of the Government of the Russian Federation dated June 07, 2023 No. 1495-r "Strategy for the development of the pharmaceutical industry of the Russian Federation for the period up to 2030". Russian

[27] The device for welding the Upress Adapt blister. Unique technologies. Available from: https://upack.pro/main-categories/packing-equipment/privarochniy-pressupress-adapt/. Russian

Maintaining the stability and expiration date of medicines, the crushing strength of tablets in an opened package in accordance with GM.1.1.0009[28] and GPM.1.1.1.0017 continue to be the most pressing issues[29].

The following question also requires a solution — will all pharmacies be allowed to work with "in bulk" medicines or only if they have a license for pharmaceutical activities — the right to production medicines for medical use. Of course, just as the preparation of powders and other dosage forms from "in bulk" medicines, their dispensing according to prescriptions and requirements of medical organizations should be carried out by compounding pharmacies or pharmacies that have prescription and production departments (PPD) in their structure. It is necessary to determine management and logistics approaches aimed to optimize the production and economic processes of a pharmacy engaged in dispensing "in bulk" medicines.

The solution to this issue is:

1. It is necessary to determine the main compounding pharmacy with geographical mapping (city, district, region);
2. Allocate budget funds for the material and technical equipment of the compounding pharmacy or the prescription and production department of the pharmacy.

The pharmaceutical organization engaged in the manufacture of extemporaneous medicines introduces into its functionality the corresponding delivery to pharmaceutical organizations, pharmacy points engaged in preferential dispensing of medicines, and structural pharmaceutical organizations of hospital institutions. The delivery of extemporaneous medicines is organized taking into account the requirements of GM.1.1.0037 Transportation of Medicines[30] using equipment and vehicles that ensure compliance with storage conditions and safety measures.

This solution will be a guarantee of ensuring the quality, effectiveness and safety of EDs, motivating pharmacies to revive PPDs, and increase their competitiveness.

A pharmacy engaged in the compounding of medicines, including the dispensing of "in bulk" medicines, must comply with all licensing requirements; rules for the manufacture, storage and dispensing of medicines for medical use; sanitary and hygienic norms and requirements; rules of good pharmacy practice. Pharmaceutical specialists must meet the qualification requirements, have a specialist certificate or accreditation certificate [38–40]. The list of the main regulatory legal documents governing this type of pharmaceutical activity is presented below.

1. Federal Law No. 99-FZ of May 4, 2011 "On Licensing Certain Types of Activities";
2. Federal Law No. 61-FZ of April 12, 2010 "On Circulation of Medicines";
3. Decree of the Government of the Russian Federation No. 547 of March 31, 2022 "On Approval of the Regulations on Licensing Pharmaceutical Activities";
4. Order of the Ministry of Health of the Russian Federation No. 249n of May 22, 2023 "Rules for the Manufacture and Dispensing of Medicines for Medical Use by Pharmacy Organizations Licensed for Pharmaceutical Activities";
5. Decree of the Chief State Sanitary Doctor of the Russian Federation No. 44 of December 24, 2020 "On approval of sanitary rules SP 2.1.3678-20 "Sanitary and epidemiological requirements for the operation of premises, buildings, structures, equipment and transport, as well as the conditions of activity of economic entities engaged in the sale of goods, performance of work or provision of services";
6. Order of the Ministry of Health of the Russian Federation No. 647n dated August 31, 2016 "On approval of the rules of good pharmacy practice for medicines for medical use";
7. Order of the Ministry of Health and Social Development of the Russian Federation dated August 23, 2010;
8. No. 706n "On approval of the Rules for the storage of medicines";
9. Order of the Ministry of Health and Social Development of Russia No. 541n dated July 23, 2010 "On approval of the Unified Qualification Directory of positions of managers, specialists and employees, section "Qualification characteristics of positions of workers in the field of healthcare";
10. Order of the Ministry of Health of the Russian Federation No. 709n dated October 28, 2022 "On approval of the Regulations on the accreditation of specialists."

Generalized labor functions and labor functions for the manufacture of EDs are prescribed in the professional standards "Specialist in the field of pharmaceutical activity management", "Pharmacist", "Pharmacy analyst", "Pharmacy technician ".

To systematize the entire process of personalized

[28] GM.1.1.0009. Stability and shelf life of medicines. The State Pharmacopoeia of the Russian Federation XV edition. Available from: https:// pharmacopoeia.regmed.ru/pharmacopoeia/izdanie-15/1/1-1/ stabilnost-i-sroki-godnosti-lekarstvennykh-sredstv/. Russian

[29] GM.1.1.1.0017. Crushing strength of tablets. The State Pharmacopoeia of the Russian Federation XV edition. Available from: https:// pharmacopoeia. regmed.ru/pharmacopoeia/izdanie-15/1/1-1/1-1-2/ prochnost-tabletok-na-razdavlivanie/. Russian

[30] GM.1.1.0037. Transportation of medicines. The State Pharmacopoeia of the Russian Federation XV edition. Available from: https:// pharmacopoeia.regmed.ru/pharmacopoeia/izdanie-15/1/1-1/ perevozka-lekarstvennykh-sredstv/. Russian

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drug assistance with EDs, including those made from medicines "in bulk", it is necessary to include unified and approved EDs prescriptions in clinical guidelines, incorporating them into state guarantee programs.

To analyze the relevance of EDs prescriptions and forecast needs, it is necessary to use the data from the federal register of citizens entitled to drug provision at the expense of budgetary allocations from the federal budget and the budgets of the constituent entities of the Russian Federation, approved by Decree of the Government of the Russian Federation No. 1656[31] dated October 12, 2020. The Ministry of Industry and Trade should study the suggestions about medicines "in bulk" on the pharmaceutical market. Applications for compounded medications will need to be handled at the regional and federal levels. The Federal Center for Planning and Supply of Medicines of the Ministry of Health of Russia [41] is engaged in the centralized procurement of medicines for orphan patients, and accordingly, medicines "in bulk" for the treatment of orphan diseases will be under its jurisdiction.

Regarding the current state of regulatory features in the field of medicine manufacturing, it seems appropriate to create an updated List of unified medical prescriptions for additional professional education of medical and pharmaceutical workers. In accordance with section II "Quality system for the manufacture of medicines" of Order of the Ministry of Health of Russia No. 249n dated May 22, 2023, it is recommended to approve the local standard operating procedure (SOP) "Packaging of medicines 'in bulk'". Special attention should be paid to the legal issues of prescribing and using medicines "off-label", including "in bulk" products [42–44].

Improving state regulation in the field of EDs circulation, conducting a flexible intra-organizational policy taking into account current needs for effective and safe pharmaceutical medicines [45–47] will contribute to the sustainable development and increased competitiveness of compounding pharmacies [48–50].

CONCLUSION

Dispensing of medicines is a promising area of pharmaceutical activity for a pharmacy. Ensuring the manufacture and dispensing of medicines should be based on scientifically proved methods and tools of the legislative framework, lead to a reduction in budgetary allocations for drug assistance, and be economically beneficial for the end consumer and the compounding pharmacy. The inclusion of packaged medicines "in bulk" in state guarantee programs will improve personalized drug provision, primarily for patients with rare orphan diseases, in the pediatric population, and in geriatric practice. Packaging of medicines "in bulk" will serve as one of the factors for the sustainability of the circulation of pharmaceutical medicines and the adaptation of drug provision in the face of new challenges and threats.

[31] Decree of the Government of the Russian Federation dated 12.10.2020 No. 1656 "On Approval of the Rules for Maintaining the Federal Register of Citizens Entitled to Provide Medicines, Medical Devices and Specialized Medical Nutrition Products at the expense of Budgetary Allocations from the Federal Budget and the Budgets of the Constituent Entities of the Russian Federation". Russian

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS' CONTRIBUTION

Rimma Yu. Garankina —objectives, conception, collection and critical analysis of scientific and regulatory legal documents, comments on the content, writing the text, editing and final approval of the manuscript; Vasily V. Ryazhenov — collection and analysis of scientific and methodological literature, critical analysis of scientific and methodological literature, comments on the content, editing the article; Elena A. Maksimkina — collection and analysis of scientific and methodological literature, critical analysis of scientific and methodological literature, comments on the content, editing the article; Victor S. Fisenko — collection of scientific and methodological literature, critical analysis of scientific and regulatory legal documents, methodological literature, comments on the content, editing the article; Aleksey V. Alekhin — collection of scientific and methodological literature, critical analysis of scientific and methodological literature, comments on the content, editing the article; Vadim V. Tarasov — collection of scientific and methodological literature, critical analysis of scientific and methodological literature, comments on the content, editing the article; Kirill A. Chizhov — data collection and analysis, editing the article; Irina F. Samoshchenkova — collection and analysis of scientific and methodological literature, comments on the content, editing the article; Nana Yu. Behorashvili — collection and analysis of scientific and methodological literature, comments on the content, editing the article; Elena R. Zakharochkina — collection and critical analysis of scientific literature and regulatory legal documents, comments on the content, editing the article, final approval of the manuscript. 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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