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# Review of BRICS regulatory practices in the field of drugs compounding

**D.S. Yurochkin[1], D.D. Mamedov[1], S.E. Erdni-Garyaev[1], A.V. Yarutkin[2], V.L. Bagirova[2], P.S. Guryanov[3], O. Ludiy[3], V. Li[4]**

[1] St. Petersburg State Chemical and Pharmaceutical University, 14A Prof. Popov Str., St. Petersburg, Russia, 197022
[2] Scientific Centre for Expert Evaluation of Medicinal Products, Bld. 2, 8 Petrovsky Blvd, Moscow, Russia, 127051
[3] Perm State Pharmaceutical Academy, 101 Ekaterininskaya Str., Perm, Russia, 614990
[4] Independent Researcher, Beijing, China

E-mail: dmitry.yurochkin@pharminnotech.com

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In the formation of a common market within the framework of interstate associations (Unions), the goal of improving the health of the member states population can be achieved, among other things, by providing an unimpeded access to safe, effective and quality medicines (drugs). One of the elements is activities in the field of these drugs compounding. This review has been prepared by authors due to the lack of information in the Russian-language literature on the regulation of this area in the current legal systems of the BRICS countries.

**The aim of the work** was to analyze the regulatory mechanisms and current approaches to the organization of activities in the field of drugs compounding, presented in the legislation of the BRICS interstate association (Union) member countries, including their structuring (systematization) in order to develop proposals for the convergence of these practices.

**Materials and methods.** PubMed, Google Scholar, elibrary.ru, and specialized databases of regulatory legal documents of the BRICS countries were used as search resources. The following keywords were used as search keywords: “drug”, “drug product”, “drugs compounding”, “pharmacy organization”, “medical organization”, “compounding”, “drug preparation”, “drug dilution (reconstitution)” in English, Portuguese, Spanish, Chinese, Arabic, Persian and Hindi. The paper uses empirical, theoretical, quantitative tools, including the analysis of a wide list of relevant sources - regulatory legal documents governing the activities of compounding pharmacies in the BRICS countries.

**Results.** The study presents key regulatory legal acts and documents, analyzes them and describes the main provisions of the legislative framework for the organization of activities in the field of drugs compounding. The identified peculiarities determine the need to rethink the current state of the Russian regulation of the drugs compounding sector. The study emphasizes the need to improve regulatory approaches in Russia. The BRICS countries can strive to develop the best practices and “gold” standards for the organization of this socially important activity in the field of drugs compounding. Such an approach can led to the creation of a unified good practice in compounding and dispensing of drugs.

**Conclusion.** The authors of the study consider it advisable to carry out a further and more detailed elaboration of the convergence issues of regulatory practices of both health care systems and pharmaceutical industries in the BRICS member states. It has been proposed to develop and form a “Roadmap” (an action plan) for the development of the cooperation between the BRICS member states in the field of health care and pharmaceutical industry in order to intensify integration processes and build a modern model of the public health and drug market, including joint research and development by world-class scientific centers for technological development of the interstate association (Union) countries.

**Keywords:** legislation; BRICS; manufacturing of pharmaceuticals; Diluting (Reconstitution) of pharmaceuticals; compounding pharmacies; drugs compounding; quality of pharmaceuticals; regulatory practice; personalized medicine; Brazil; India; China; Republic of South Africa; United Arab Emirates; Iran; Egypt; Ethiopia

**Abbreviations:** PO – pharmacy organization; SP – stock preparation; WTO – World Trade Organization; EEU – Eurasian Economic Union; DF – dosage form; FDF – finished dosage form; RPPs – radiopharmaceutical preparations; SOP – Standard Operation Procedure; MO – medical organization; SCO – Shanghai Cooperation Organization; DS – drug substance; CDP – compounded drug product; GMP – Good Manufacturing Practice; GPhP – Good Pharmacy Practice.

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ОБЗОРЫ

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# Обзор практик нормативного правового регулирования стран БРИКС в сфере изготовления лекарственных препаратов

**Д.С. Юрочкин[1], Д.Д. Мамедов[1], С.Э. Эрдни-Гаряев[1], А.В. Яруткин[2], В.Л. Багирова[2], П.С. Гурьянов[3], О. Лудий[3], В. Ли[4]**

[1] Федеральное государственное бюджетное образовательное учреждение высшего образования «Санкт-Петербургский химико-фармацевтический университет» Министерства здравоохранения Российской Федерации, 197022, Россия, г. Санкт-Петербург, ул. Профессора Попова, д. 14, лит. А
[2] Федеральное государственное бюджетное учреждение «Научный центр экспертизы средств медицинского применения» Министерства здравоохранения Российской Федерации, 127051, Россия, г. Москва, Петровский б-р, д. 8, стр. 2
[3] Федеральное государственное бюджетное образовательное учреждение высшего образования «Пермская государственная фармацевтическая академия» Министерства здравоохранения Российской Федерации, 614990, Россия, г. Пермь, ул. Екатерининская, д. 101
[4] Независимый исследователь, г. Пекин, Китай

E-mail: dmitry.yurochkin@pharminnotech.com

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При формировании общего рынка в рамках межгосударственных объединений (союзов) цель укрепления здоровья населения государств-членов может достигаться, в том числе, путём обеспечения беспрепятственного доступа к безопасным, эффективным и качественным лекарственным препаратам (ЛП). Одним из элементов выступает деятельность в сфере изготовления ЛП. Ввиду недостаточного объёма сведений в русскоязычной литературе о регулировании этой сферы в действующих правовых системах стран БРИКС, авторами подготовлен настоящий обзор.
**Цель.** Провести анализ действующих подходов и механизмов регулирования к организации деятельности в сфере изготовления ЛП, представленных в законодательстве стран-участниц межгосударственного объединения (союза) БРИКС, включая их структурирование (систематизацию) для выработки предложений по сближению данных практик.
**Материалы и методы.** В качестве поисковых ресурсов были использованы базы данных PubMed, Google Scholar, elibrary.ru, а также специализированные базы данных нормативных правовых документов стран БРИКС. В качестве ключевых слов для поиска использовали: «лекарственное средство», «лекарственный препарат», «изготовление лекарственных препаратов», «аптечная организация», «медицинская организация», «компаундинг», «приготовление лекарств», «разведение (восстановление) лекарственных препаратов» на английском, португальском, испанском, китайском, арабском, персидском языках и хинди. В работе использованы эмпирические, теоретические, количественные инструменты, включая анализ широкого перечня релевантных источников – нормативных правовых документов, регулирующих деятельность производственных аптек в странах БРИКС.
**Результаты.** В исследовании представлены ключевые нормативные правовые акты и документы, проведён их анализ, а также описаны основные положения законодательной базы по организации деятельности в сфере изготовления ЛП. Выявленные особенности определяют потребность в переосмыслении текущего состояния российского регулирования сферы изготовления ЛП. Исследование подчеркивает необходимость совершенствования регуляторных подходов, действующих в России. В сфере изготовления ЛП страны БРИКС могут стремиться к выработке лучших практик и «золотых» стандартов по организации данного социально значимого вида деятельности. Такой подход может привести к созданию единой надлежащей практики изготовления и отпуска ЛП.
**Заключение.** Авторы исследования считают целесообразным выполнение дальнейшей и более детальной проработки вопросов сближения регуляторных практик как систем здравоохранения, так и фармацевтических отраслей стран-участниц БРИКС. Предложено разработать и сформировать «Дорожную карту» (план мероприятий) по развитию взаимодействия государств-участников БРИКС в области здравоохранения и фармацевтической отрасли. В целях интенсификации интеграционных процессов и выстраивания современной модели общественного здоровья и рынка обращения ЛС, включающего проведение совместных исследований и разработок научными центрами мирового уровня для технологического развития стран межгосударственного объединения (союза).

**Ключевые слова:** законодательство; БРИКС; изготовление лекарственных препаратов; разведение (восстановление) лекарственных препаратов; производственные аптеки; экстемпоральные лекарственные препараты; качество лекарственных средств; регуляторная практика; персонализированная медицина; Бразилия; Индия; Китай; Южно-Африканская Республика; Объединенные Арабские Эмираты; Иран; Египет; Эфиопия

**Список сокращений:** АО – аптечная организация; ВАЗ – внутриаптечная заготовка; ВТО – Всемирная торговая организация; ГЛФ – готовая лекарственная форма; ЕАЭС – Евразийский экономический союз; ЛП – лекарственный препарат; ЛС – лекарственное средство; ЛФ – лекарственная форма; РФЛП – радиофармацевтические лекарственные препараты; СОП – стандартная операционная процедура; МО – медицинская организация; ШОС – Шанхайская организация сотрудничества; ФС – фармацевтическая субстанция; ЭЛП – экстемпоральный лекарственный препарат; GMP – Надлежащая производственная практика; НАП – надлежащая аптечная практика.

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## INTRODUCTION

An interstate association (Union), the BRICS (BRICS+) transregional partnership (community) was founded on the initiative of the Russian Federation (RF) in June, 2006. In 2013, the Concept of the Russian Federation's participation in the BRICS[1] association was adopted, which is one of the strategically significant directions of long-range foreign policy activities, and the National Committee on the BRICS Research was established. Among the priority areas of the Russian Federation's state policy and BRICS initiatives, the cooperation in the sphere of health care, public health protection, development, introduction of new medical technologies and medicines (drugs), is of particular importance. According to this concept, the main aims in the development of the interaction and cooperation with other BRICS member states have been established: in the pharmaceutical industry (the development and production of modern types of drugs); in the field of health care (strengthening health care systems and expanding an access of the population to high-quality, effective and safe medicines, vaccines and other drugs).

As of October 2024[2], the BRICS comprises 9 states: the Federative Republic of Brazil (Brazil), Russian Federation, Republic of India (India), People's Republic of China (China), Republic of South Africa (South Africa), United Arab Emirates (UAE), Islamic Republic of Iran (Iran), Arab Republic of Egypt (Egypt), and Federal Democratic Republic of Ethiopia (Ethiopia). At the time of this study completion, the XVI$^{th}$ BRICS summit was held from October 22 to 24, 2024, in Kazan, Russia. At the same time, the countries invited to join the association included the Kingdom of Saudi Arabia, which had not confirmed its membership in BRICS, and the Republic of Argentina, which had declined to join. At the BRICS summit in Russia in 2024, a new category of BRICS-related states was proposed – 13 states (Algeria, Belarus, Bolivia, Cuba, Indonesia, Kazakhstan, Malaysia, Nigeria, Thailand, Turkey, Uganda, Uzbekistan, Vietnam) were granted the status of "BRICS partner countries". Following the XVI$^{th}$ BRICS Summit, on 23 October 2024, the "Kazan Declaration on Strengthening Multilateralism for Equitable Global Development and Security"[3] was signed, according to which the decision of the Consultative Group on the New Industrial Revolution to establish seven working groups, comprising the ones on medical devices and pharmaceuticals, was supported. The declaration welcomes the establishment of closer ties between the BRICS health institutions responsible for sanitary and epidemiological health and well-being, the prevention of infectious diseases, and calls for a further exploration of opportunities to share knowledge and expertise, and to implement joint projects in the health sector. The BRICS countries have made a great contribution to establishing a close cooperation in the tuberculosis and antibiotic resistance control, capacity building in the infectious disease prevention and other areas such as non-communicable diseases, research and development, exchange of experience, including the problems on traditional medicine, digital health, nuclear medicine, radiopharmaceuticals (with a special emphasis on strengthening radiopharmaceutical supply chains and expanding an isotope production, as well as contributing to the development of advanced digital solutions).

The above-mentioned areas, together with stimulating the development of health care systems, are a harmonious continuation of the human capital development aims set out in the structure of priority areas of the BRICS Economic Partnership Strategy up to 2025[4]. The BRICS countries, including the Russian Federation, have created all the necessary conditions for the development of scientific and technological competencies in the production of medicines, raw materials, materials, equipment, components, as well as drugs compounding, including radiopharmaceutical preparations (RPPs)[5]. The growing and significant role of the unique interstate association (Union) BRICS has been regularly emphasized in the works devoted to the development of diplomatic relations of Russia, speeches at forums, summits of various levels and Addresses of the President of the Russian Federation to the Federal Assembly since 2011[6,7] [1].

[1] CONCEPT of participation of the Russian Federation in BRICS. Available from: http://kremlin.ru/events/president/news/17715

[2] BRICS Intergovernmental Organization. Available from: https://brics-russia2024.ru/about/

[3] Kazan Declaration "Strengthening multilateralism for just global development and security". Available from: http://static.kremlin.ru/media/events/files/ru/MUCfWDg0QRs3xfMUiCAmF3LEh02OL3Hk.pdf

[4] The BRICS Economic Partnership Strategy until 2025. Available from: https://www.economy.gov.ru/material/file/636aa3edbc0dcc2356ebb6f8d594ccb0/1148133.pdf

[5] Decree of the Government of the Russian Federation dated 7 June 2023 No. 1495-r «On the Strategy for the development of the pharmaceutical industry of the Russian Federation for the period up to 2030». Available from: https://docs.cntd.ru/document/1301897806

[6] Message of the President of the Russian Federation to the Federal Assembly of the Russian Federation at 22 Dec 2011. Available from: http://kremlin.ru/events/president/news/14088

[7] Message of the President of the Russian Federation to the Federal Assembly of the Russian Federation at 29 Feb 2024. Available from: http://www.kremlin.ru/acts/bank/50431

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As the practice of international organizations of regional and economic integration has shown, when forming a common market, the goal is to improve the population health in the member states of the interstate association (Union). This goal can be achieved, among other things, by providing an access to safe, effective and high-quality medicines, recognizing the expediency of a coordinated policy in the sphere of the drug circulation, taking into account mutual interest, due to the fact that medicines are socially important products. One of the elements in the sphere of the drug circulation is the activity in the sphere of drugs compounding, which has a high potential in the transition from the accounting of "packages" to the accounting of the volume of course prescriptions in the use of drug therapy, which simultaneously contributes to the optimization of resources and the development of personalized medicine, high-tech health care and health-saving technologies [2]. The greatest need among pediatric patients is in the segment of liquid oral dosage forms that provide an age-appropriate dosing and the administration convenience of [3]. Herewith, drugs compounding can be carried out by both pharmacy organizations (POs) and medical organizations (MOs). In the world practice, it is defined by the concept of "hospital exemptions" [4, 5]. Due to the personalization of dosages, combinations of active substances, dosage forms (DFs) and packaging volumes, compounded drug products (CDPs) belong to unregistered types of drugs.

A number of works by Russian researchers have been devoted to the study of various aspects of drug circulation in the BRICS countries. In terms of the peculiarities of an expanded access for unregistered drugs within the framework of a compassionate use and provision of therapy in the context of early access programs, including the BRICS countries, the study by Omelyanovsky V.V. et al. is of interest. [6]. The paper shows approaches to the accelerated registration and registration of medicines with insufficient clinical data, describes the practices of the countries under consideration for early access programs. The issues of quality assurance and safety, the organization and implementation of a quality control in the BRICS countries are of particular importance. An up-to-date review of the current joint activities of the Federal Service for Supervision of Health Care (Roszdravnadzor), the Ministry of Health of Russia and the Ministry of Industry and Trade of Russia on the results of the participation in specialized activities of the BRICS countries, in particular, in consultations to discuss the draft Memorandum of Understanding and Cooperation in the field of the medical products regulation between the regulatory authorities of the BRICS countries, is presented in the work by Samoylova A.V. and Kudryavtseva E.M. [7]. From the point of view of the pharmaceutical industry, a special role is played by the requirements for the quality system in the structure of Good Manufacturing Practice (GMP) and GMP inspectorate procedures, which is presented in the work by V.N. Shestakov and Y.V. Podpruzhnikov. [8]. This study summarizes international recommendations in this area; an additional professional retraining program for specialists "Rules of organizing production and quality control of drugs – theory and practice of a GMP-inspection / audit" has been developed, approved of and tested. An equally important issue is also the order and principles of price regulation systems for registered MPs in the BRICS countries, the study and identification features of which the work by Gorin S.F. et al. [9] is devoted to. Despite the fact that the main group of domestically produced MPs is represented by reproduced MPs, the researchers come to the conclusion that confirms the need for a further cooperation between Russia and major economic alliances – EEU and BRICS [10] on the issues of organizing the production of raw materials of a pharmaceutical quality for the MPs manufacturing.

To study the normative legal regulation of health care systems in the BRICS countries, the research on the example of Brazil t has been conducted. For example, the work by S.A. Belousov and E.A. Tarasova [11] notes the country's experience in developing a modern public health care system and creating conditions of an equal accessibility to medical care for all segments of the population, highlighting the experience of individual social systems. In the light of the provisions of a number of normative and judicial acts of general and special character in the field of the public health care, the provision of drugs to the population and the protection of industrial property rights, the issues of a patent law validity are one of the decisive ones when exporting technological solutions or products. In this regard, in relation to pharmaceutical products, the key legal problems and ways to solve them before and after the accession of one of the BRICS countries (Brazil) to the World Trade Organization (WTO) are detailed in the work by Belikova K.M. [12]. Speaking about the diversification of partnerships and the intensification

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of the already existing international contacts, including the expansion of institutional partnerships within the Russian Federation, the focus on a deeper interaction with friendly partners (EEU countries, BRICS, Shanghai Cooperation Organization – SCO) in the context of this study, the work by Belov F.D. and Zvolinskaya O.V. presents the results of monitoring the activities of world-class research centers in the priority area – "Personalized medicine, high-tech healthcare and health-saving technologies" for 2020–2022 [13].

The recent works devoted to the prospects of improving the legislation on manufacturing medicines in the Russian Federation, should be also noted. A profound and strategically significant assessment of the work in this direction is presented by the head of the working group on the revival of compounding pharmacies at the Health Protection Committee of the State Duma of the Federal Assembly of the Russian Federation, the deputy of the State Duma of the VIII$^{th}$ convocation, Doctor of Sciences (Medicine), Associate Professor, Honored Physician of the Republic of Tatarstan, A.Z. Farrakhov. [14]. Modern and prospective pharmacopoeial requirements for the quality of compounded drug products (CDPs) are presented in the work by Shishova L.I. et al. [15]. Nevertheless, due to the insufficient amount of information in the Russian-language literature on the regulation of drug manufacturing in the current legal systems of the BRICS countries, it was concluded that the actual aim of this study was to improve the understanding and knowledge of Russian regulators, specialists in the field of health care organizations, public health, pharmacy, as well as medical and pharmaceutical professionals regarding the legal requirements for POs and MOs engaged in manufacturing activities on the territory of the BRICS countries, including requirements for the creation of a modern, high-tech healthcare infrastructure capable of manufacturing necessary and demanded types of MPs from highly toxic (hazardous) substances.

This article provides systematized information on the key features of regulation in manufacturing of drugs, as well as allows to develop an effective list of priority measures to achieve prospective and joint goals of the BRICS commonwealth in the development of the interaction between the MPs research and the development sectors, building cooperation ties covering the entire life cycle of pharmaceutical products between the countries of the interstate association (Union) in the field of personalized, predictive and preventive medicine, high-tech healthcare and health-saving technologies, including the rational use of MPs (primarily antibacterial drugs). The present study meets one of the key aims of the Russian cooperation in the BRICS association – to strengthen scientific and technological independence through the development of a hyperlocal healthcare infrastructure in the field of drug manufacturing, which also stimulates a domestic production of MPs, medical devices, machinery and equipment, and thus contributes to the achievement of the targets for increasing a trade turnover between the states of the interstate association (Union). In case decisions are made on the formation of common principles and rules for the drug circulation in the BRICS countries to form a common market, the results of the work can serve as a basis for the harmonization of regulatory approaches for MOs and POs in the organization of activities for manufacturing of drugs. The study promotes the progress towards the convergence of regulatory requirements for the drug circulation in the BRICS member countries, allows to deepen understanding and familiarize with the experience of organizing activities in the field of individual and small-scale drug manufacturing of different classes (radiopharmaceuticals, biologics, biotechnology, high-tech and other types of drug therapy). The joint efforts of the authors are aimed at developing balanced proposals to stimulate research and development of technologies for individual drug manufacturing, personalized reconstitution (dilution) and in-pharmacy packaging of registered drugs (finished dosage forms, FDFs), as well as in general to improve the competitiveness of domestic technological solutions and developments, to accelerate the development of new competencies in the domestic pharmaceutical industry.

Turning to the study of the of the legal regulation experience of the BRICS countries in drug manufacturing, it is important to note that a further development of pharmaceutical activities with the right of manufacturing drugs can be considered in terms of different ways of classification and organization of the licensing system. To date, there are two main approaches to the regulation of compounding pharmacies:

1. In the structure of the North American regulation, where POs are divided into two lists — 503A and 503B, taking into account that the latter must comply with GMP requirements, where a number of GMP provisions and requirements are inapplicable to the activities of compounding

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pharmacies due to the peculiarities of pharmacy technologies, quality control methods used and an individualization of pharmacotherapy to the needs of a particular patient.

2. In the European regulatory structure, which uses the concept of risk levels based on which different requirements are set for processes, premises, equipment, analytical methods, a quality assurance system and, accordingly, the requirements for different classes of active substances are separated according to their toxicity level within the framework of the Good Pharmacy Practice (GPHP) system.

The above models are discussed in detail in the previous works by the author's teams [16–19], including the Russian experience of organizing drug manufacturing activities [16, 20].

In the vast majority of the BRICS countries, similar to the Russian practice, there is a two-tier system of education of pharmaceutical specialists. At the same time, a few certain differences which are not the main subject of this study and not included in the final scope of work, have been identified. Therefore, the authors decided to simplify the reader's perception of these features by using in the text the definitions "pharmacist" to denote specialists with higher pharmaceutical education, and "pharmacist assistant", as specialists with secondary pharmaceutical education, as well as their common aggregate in the form of a "pharmaceutical specialists". In addition, the BRICS countries have created conditions for recording information about staffing and employment of these specialists. This information is organized in the relevant state registers: employees are required to undergo the accreditation procedure to obtain the admission to pharmaceutical activities and to master periodic professional development programs, which conceptually also corresponds to the procedures adopted in Russia [21]. This paper presents some key features of pharmaceutical education and conditions of specialists admission to pharmaceutical activities. The article by Mandrik M.A. et al. details the state of educational programs, the international experience and current trends in drug manufacturing as the factors that initiate the transformation of pharmaceutical education [22].

For the purpose of the unification, it was also decided to use the definitions "a hospital pharmacy" to denote a pharmacy, which is a structural subdivision of a medical organization of any ownership form, and "a public pharmacy", as a pharmacy that carries out a retail trade (dispensing), primarily in outpatient settings, which also meets the international conceptual apparatus.

**THE AIM** of the work was to analyze the regulatory mechanisms and current approaches to the organization of activities in the field of drugs compounding, presented in the legislation of the BRICS interstate association (Union) member countries, including their structuring (systematization) in order to develop proposals for the convergence of these practices.

## MATERIALS AND METHODS

Empirical, theoretical, quantitative methodological tools were used in the work. In particular, a wide list of relevant information sources was analyzed; information from regulatory legal documents governing the activities of compounding pharmacies in the BRICS countries, implemented by a bibliometric method, was also obtained.

The authors analyzed regulatory legal documents and databases of Brazil[8,9], India[10], China[11,12], Republic of South Africa[13,14], UAE[15], Iran[16], Egypt[17], Ethiopia[18,19] available in the open sources.

The search was performed using the following keywords: "drug", "drug manufacturing", "pharmacy organization", "medical organization", "compounding", "drug preparation", "drug dilution (reconstitution)" in English, Portuguese, Spanish, Chinese and Arabic.

To analyze the results of studies by other authors, relevant sources of information and data from the following search engines — biomedical research PubMed, a scientific electronic library elibrary.ru, Google Academy, were used. Similar key queries were

[8] The president of the Republic. Available from: https://www.gov.br/planalto/pt-br
[9] Brazilian Health Regulatory Agency. Available from: https://antigo.anvisa.gov.br/
[10] Ministry of Health and Family Welfare, Government of India. Available from: https://mohfw.gov.in/
[11] State Administration of Market Regulation. Available from: https://www.samr.gov.cn/
[12] National Health Commission of the PRC. Available from: http://en.nhc.gov.cn/
[13] South African Government. Available from: https://www.gov.za/
[14] The Southern African Legal Information Institute. Available from: https://www.saflii.org/
[15] UAE Legislation. Available from: https://uaelegislation.gov.ae/
[16] The Ministry of Health and Medical Education. Available from: https://behdasht.gov.ir/
[17] Egyptian Drug Authority. Available from: https://edaegypt.gov.eg/
[18] Ethiopian Food and Drug Authority. Available from: http://www.efda.gov.et/
[19] Ethiopian Legal Information Portal. Available from: https://www.lawethiopia.com/

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also used for the search.

The literature and normative legal documents were searched for the period of 1900–2024; the choice of the period was due to the specifics of the publication of legislative acts in the BRICS countries. The key, but not exhaustive, criteria for recognizing normative legal documents, legislative acts as relevant and for their further consideration, were the presence of provisions on (about) in them: a regulation of MPs circulation issues, organizing medical and POs, specifics of the procedure and requirements for licensing (premises, equipment, processes, personnel, etc.), rules / practices for manufacturing, a quality control and dispensing of medicines.

According to the specified directions and keywords, 1875 sources of information were found; after excluding invalid data, the final review included 50 most relevant works in relation to the above criteria.

## RESULTS AND DISCUSSION

### Brazil

According to Brazilian Law No. 5991 dated 17 December 1973[20], there are two kinds of POs: the ones with the right of compounding drugs and the POs dealing with FDFs.

The performance of POs pharmaceutical activities in Brazil is regulated by two main legal regulations:

- Decision of the Collegial Council of the National Agency for Health Surveillance of Brazil No. 44 dated August 17, 2009[21] – describes the basic requirements for FDFs retail sale and is identical in its content to the Rules of Good Pharmacy Practice of Drugs (hereinafter – Order No. 647)[22] in Russia;
- Decision of the Collegial Council of the National Health Surveillance Agency of Brazil No. 44 dated October 8, 2007[23] (hereinafter – GMP of Brazil) – represents the GMP Rules for manufacturing MPs.

The Brazilian GPhPs contains an extensive conceptual framework dedicated to drug manufacturing activities, including the following definitions: “pharmaceutical care”, “pharmaceutical services”, “drug dispensing”, “regulatory documentation”, “standard operating procedures” (SOPs) [23], “officinal” and “magistral formulation” [16], “classified premises”, “validation”, “verification”, etc. [16].

Annex No. 1 of Brazilian GPHP structurally and substantively repeats the main chapters of GMP, and also discloses the specifics related to POs activities in the field of drug compounding. For example, basic provisions and requirements are established for (including, but not limited to): premises of the compounding pharmacy, equipment and SOPs, labeling of raw materials, etc.

The key features of the above Annex No. 1, as applied to the present study, are:

1. Possibility to use scientific literature in the absence of necessary pharmacopoeial monograph (general and (or) private), as well as the realized right of POs to carry out an independent development of necessary specifications for raw materials, quality control methods for CDPs.
2. Purified water is subjected to a full pharmacopoeial analysis at least once a month.
3. Mandatory kinds of a quality control for non-sterile DFs compounded for a particular patient by prescription, are carried out according to the following indicators: a description, organoleptic properties, an average mass (volume), pH (if applicable), mass (volume) of CDPs, mass (volume) of semi-finished products before packaging. At the same time, a full pharmacopoeial quality control of such drugs is carried out at least once every 3 months.
4. Each series of MPs compounded as a stock preparation (SP) shall be evaluated for the following: organoleptic properties; pH (if applicable); an average weight and/or volume; viscosity (if applicable); ethanol content (if applicable); density (if applicable); a quantitative analysis of a drug substance (DS); microbiological purity (if applicable).

In this case, a PO must necessarily have a technical possibility, necessary equipment and materials to ensure the quality of compounded drugs in accordance with the above subparagraphs. An assessment of a quantitative composition and microbiological purity can be carried out in an outsourcing laboratory (center) of a MP quality control. A documented in-pharmacy control shall be

[20] Law No. 5991 of 17 December 1973. Available from: https://www.planalto.gov.br/ccivil_03/leis/l5991.htm?hidemenu=true
[21] Resolution of the Collegial Council of the RDC No. 44 dated August 17, 2009. Available from: https://antigo.anvisa.gov.br/legislacao#/visualizar/28425
[22] 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 of Medicines for medical use”. Available from: https://docs.cntd.ru/document/420377391
[23] Resolution of the RDC Board No. 67 dated November 08, 2007. Available from: https://antigo.anvisa.gov.br/legislacao#/visualizar/28030

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carried out during compounding stock SPs. There is no minimum sample size for quality control purposes and it should be statistically representative for the size of the series to be compounded.

Annex No. 2 of the Brazilian GPHP establishes requirements for compounding drugs with "a low therapeutic index" (port. Substâncias de Baixo Índice Terapêutico), i.e. the drugs characterized by a high biological activity with a minimal change in dosage (valproic acid, aminophylline, carbamazepine, cyclosporine, clindamycin, etc.). Thus, for example, in the specified document, there is a requirement to use the smallest size of capsules containing drugs of this type.

Annex 3 of the Brazilian GPHP, which establishes the minimum requirements necessary for handling the CDPs made from hormonal MPs, antibiotics and cytostatic substances, is of particular importance. The Annex prescribes a mandatory availability of different compounding premises with an airlock for all classes of the listed substances and independent air supply systems (heating, ventilation and air conditioning (HVAC)). Such premises must be negatively pressurized in relation to the adjacent compounding premises and designed to prevent bulk substances from entering other areas of the compounding pharmacy.

Annex No. 4 of the Brazilian GPHP is devoted to the compounding of sterile DFs, which is structurally and content-wise fully similar to Chapter 797 of the US Pharmacopoeia. The requirements for compounding premises in terms of a microbiological purity and the number of particles in the air correspond to the GMP requirements. The same document specifies the main parameters of compounding highly toxic MPs corresponding to Chapter 800 of the US Pharmacopoeia. A detailed review of the US Pharmacopeia in terms of drug compounding is presented in the monograph [16] and the article on pharmacy drug compounding in the USA [17].

Annex No. 5 of the Brazilian GPHP describes the basic requirements established for homeopathic MPs. Annex 6 of the Brazilian GPHP establishes requirements for MP reconstitution (dilution) processes.

According to the Decision of the Collegial Council of the National Agency for Health Surveillance No. 63 dated December 18, 2009[24], RPPs compounding is carried out in hospital (at a MO) (hereinafter - hospital pharmacy), or retail / outpatient (outside a MO) (hereinafter – compounding pharmacies) in compliance with the requirements of a radiation safety and the rules of good practice in RPPs compounding. The admission to this type of activity is carried out by undergoing additional professional education.

### India

When considering the legislation of India, the peculiarities of circulation, organization of production and manufacturing "traditional" MPs, which occupy a significant part in the structure of the Indian health care system – Ayurvedic, Siddha and Unani MPs [24–26], were not included in the present study.

According to clause "f)" of Article 3 of the Indian Medicines and Cosmetics Act dated 10 April 1940[25], the concepts of "manufacturing" and "production" are separated in the meaning, similar to the Russian legislation on the circulation of MPs.

According to Sections 6, 12, 33 and 33-N of the Act referred to, the Central Government of India is empowered to frame rules for the circulation of MPs. One of the main documents is the "MPs and Cosmetics Rules" (hereinafter referred to as the Indian Rules)[26].

To obtain a license for opening a pharmacy, the licensee must meet the requirements for premises, equipment, staff qualifications and other features set out in Annex No. N of the Indian Rules. When issuing a license for opening a pharmacy, the licensing authority shall take into account the average of licenses issued or reinstated during the last three years, i.e. the rule of limiting the number of pharmacies by a geographical area may be applied.

According to Article 3 of the Indian Pharmacy Act dated 4 March 1948[27] (hereinafter referred to as the Indian Pharmacy Act), the Central Government of India forms the Pharmacy Council of India, which has the power to make regulations in accordance with the Act. The core business of manufacturing MPs is governed by Good Pharmacy Practice Rules of India (hereinafter referred to as GPHP of India)[28] approved by the Pharmacy Council of India.

GPHP of India interprets "compounding" as a

[24] Resolution of the CRD No. 63 dated December 18, 2009. Available from: https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2009/rdc0063_18_12_2009.html

[25] The Drugs And Cosmetics Act, 1940. Available from: https://indiankanoon.org/doc/1891720/

[26] The Drugs and Cosmetics Rules, 1945. Available from: https://indiankanoon.org/doc/16293633/

[27] The Pharmacy Act, 1948. Available from: https://indiankanoon.org/doc/549550/

[28] REGD. No. D. L.-33004/99. Available from: https://www.pci.nic.in/pdf/Pharmacy%20Practice%20Regulations.pdf

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process of preparation, mixing, packaging or labeling an MP or an article used: according to a prescription for an MP written by a health care provider, or at the request of an individual [18, 19] for an over-the-counter MP; or for the purpose of carrying out research, development, including training processes, conducting clinical trials, chemical analysis of an MP, but not intended for sale or dispensing.

It seems appropriate to pay special attention to the accepted qualifications of pharmacists in India. According to the Indian Pharmacy Act, the following types of accredited professionals are recognized:

1. "Public pharmacist" – provides pharmaceutical counseling and dispensing of prescription drugs in a public pharmacy.
2. "Hospital pharmacist" - functions within a PO as a structural subdivision of the MO, provides the latter with the necessary goods of the pharmacy assortment, takes part in the pharmaco-economic substantiation of the drug therapy choice.
3. "Consultant pharmacist" – provides pharmaceutical counseling and dispensing of over-the-counter drugs in a public and/or hospital pharmacy.
4. "Clinical pharmacist" - provides pharmaceutical counseling, providing patients with information on indications, contraindications for use, precautions, features, possible adverse reactions in the use of drugs, and promotes health, well-being and prevention of diseases in order to optimize treatment.

The provisions of Article 65 of the Indian Regulations stipulate that MPs compounding must be carried out under the supervision of a pharmacist, and only a pharmacist may prepare MPs containing substances from Annexes H (a list of prescription MPs) and X (e.g. amphetamine) of the Indian Regulations in accordance with Article 8.1 of the GPHP of India.

According to the survey conducted by the Indian Institute of Health Management and Research, Bangalore [27], it is shown that only 66 hospitals out of 107 follow the recommendations of FIP/W.H.O. [28, 29] or the GPHP of India, which is only 62% of the total sample.

Having comprehensively studied various aspects of the organization of drug compounding activities, the authors came to the conclusion that the regulation of this activity in India is in the initial stage of development, which began in 2015 – the GPHP of India was adopted, which established requirements for education programs, qualification levels of pharmaceutical specialists, the order of interaction of pharmaceutical boards. In addition, in India, there are various types of methodological guidelines from professional associations, compliance with which has a recommendatory nature.

### China

In the People's Republic of China, Articles 69–76 of the Law dated 20 September 1984, on the Control of Medicines (hereinafter referred to as the Chinese Law)[29] are devoted to drug compounding, according to which this type of activity can be carried out exclusively by MOs. At the same time, the latter must obtain a license for drug compounding, which is a part of the medical activity. Only pharmacists are allowed to be involved in drug compounding processes. MOs holding a license for drug compounding must develop and implement a quality assurance system. However, a substitution of any raw material in a prescription may only be made after a consultation with the treating physician. In addition, a transfer of CDPs between different unrelated MOs is allowed. According to Clause 27 of Order No. 26[30] of the State Food and Drug Administration of China (hereinafter referred to as CFDA) [30] dated 31 January 2007, dispensing of compounded MPs is allowed to patients in the MOs where they are compounded, and the transfer of CDPs to third-party MOs must be approved by the regional health authority. At the same time, the sale of CDPs to wholesale organizations and POs is prohibited.

Based on the provisions of Articles 20–27 of China's Law Enforcement Regulations[31], China has a two-tiered process for obtaining a license for drug compounding, where the immediate licensing procedure is preceded by an inspection of MPs by regional health authorities.

CFDA Order No. 20 dated 22 June 2005 (hereinafter referred to as Order No. 20)[32] established a ban on the drug compounding of registered MPs; the MPs containing

[29] Drug Administration Law of the People's Republic of China at 20 Sep 1984. Available from: https://www.gov.cn/xinwen/2019-08/26/content_5424780.htm

[30] Order of the State Food and Drug Administration No. 26 at 31 Jan 2007 "Measures for the Supervision and Administration of Drug Circulation". Available from: https://www.gov.cn/ziliao/flfg/2007-02/15/content_527789.htm

[31] Implementing Regulations of the Drug Administration Law of the People's Republic of China at 2 March 2019. Available from: https://www.gov.cn/gongbao/content/2019/content_5468873.htm

[32] Order of the State Food and Drug Administration No. 20 at 22 June 2005 "Administrative Measures for the Registration of Preparations in Medical Institutions (trial implementation)". Available from: https://www.gov.cn/gongbao/content/2006/content_292146.

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narcotic drugs, psychotropic and toxic substances; and RPPs.

In view of clauses 7, 19–25 of Order No. 20, the specific composition of the CDPs compounded in MOs must be registered by the regional health authorities, for which a special form must be filled out and sent to these state authorities. The CDPs registered for the first time must undergo clinical trials on the basis of MOs on at least 60 patients, upon the completion of which a summary report on the results of clinical trials must be submitted to the regional health authorities.

In case of natural calamities, epidemics, emergencies or clinical cases, when MPs (deficiency) required for treatment of the population are not available within one province [31], by order of the regional public health authorities, the MO is allowed to manufacture and dispense all types of MPs without any restrictions, which is established in item 26 of Order No. 20. Drug manufacturing must be carried out according to the approved SOPs, which are submitted together with a special form when CDPs are registered by the regional public authorities.

The quality of MPs manufactured in medical organizations shall comply with the Chinese Pharmacopoeia[33] and the requirements of the Good Manufacturing Practice for MPs in MOs approved by CFDA Order No. 27 dated 13 March 2001 (hereinafter referred to as China's GPhP)[34].

China's GPHP is an adaptation of GMP rules applicable to MPs compounding activities, which establishes: a personal responsibility of the chief physician for safety and quality in the use of prescribed CDPs; the need to allocate separate premises for MPs compounding and a ban on combining the head of compounding and a quality control in one person; the formation of different production zones (premises) for MPs compounding using active substances of different classes and DFs; measures to prevent cross-contamination; and the introduction of a cleanroom classification compliant with GMP requirements, etc.

In general, China's GPHP is similar to the regulation of POs type 503A in the USA [16, 17]. As noted above, compounding of RPPs without a manufacturing license is prohibited in China.

**United Arab Emirates**

The UAE is a constitutional federation consisting of seven emirates [32]. Medical and pharmaceutical licensing processes are regulated by the UAE Ministry of Health and Prevention [33], the Abu Dhabi Department of Health and the Dubai Health Authority. Until 2014, each authority had separate and independent requirements for licensing procedures[35] and in general approaches to the organization of the health care system [34], which have now been unified into one set of standards and requirements for all health care professionals, including pharmaceutical specialists.

In the scientific search of the regulatory legal documents governing the health sector throughout the UAE, it was found that there are 29 legislative acts, executive decrees and regulatory requirements of subordinate organizations, 23 of which have been adopted since 2019 (an active phase of the centralization of regulation) until now[36,37,38,39,40].

Article 1 of the UAE Federal Law No. 8 dated 19 December 2019. "On Medicines, Pharmaceutical Activities and Pharmaceutical Organizations"[41] (hereinafter – UAE Law) establishes the main definitions and concepts used in the field of the drug circulation. The definition of "Pharmaceutical profession" fixed by the legislation is a health profession (specialties) aimed at improving the level of health of citizens through the implementation of pharmaceutical advice on the correct or optimal use of MPs based on scientific specialized knowledge. As follows from the definition, a pharmaceutical profession in the UAE has a systemic role, functions and tasks that correspond to a deep integration into the activities of the health care sector, which, from the point of view of the Russian legislation, could be enshrined in the legislation on the fundamentals of a public health protection as pharmaceutical care. Types of pharmaceutical profession are defined by the

[33] National Pharmacopoeia of China. Available from: https://ydz.chp.org.cn/

[34] Order No. 27 "Quality management specifications for the preparation of preparations in medical institutions (trial implementation)" at 13 March 2001. Available from: https://www.gov.cn/zhengce/2021-06/30/content_5723541.htm

[35] Ministry of Health, Health Authority of Abu Dhabi, & Dubai Health Authority (2014) Healthcare professional qualification requirements 2014, United Arab Emirates: Author; P. 1–123. Available from: https://ru.scribd.com/doc/276006215/Healthcare-Professionals-Qualification-Requirements-PQR-2014-1

[36] Federal Law on the Public Health. Available from: https://uaelegislation.gov.ae/en/legislations/1456

[37] Federal Law Concerning the Use of the Information and Communications Technology in Health Fields. Available from: https://uaelegislation.gov.ae/en/legislations/1209

[38] Federal Law Concerning Private Health Facilities. Available from: https://uaelegislation.gov.ae/en/legislations/1204

[39] Federal Law Regulating the Practice of the Medical Profession. Available from: https://uaelegislation.gov.ae/en/legislations/1201

[40] Federal Law on Veterinary Products. Available from: https://uaelegislation.gov.ae/en/legislations/1207

[41] Federal Law on Medical Products, Pharmacy Profession and Pharmaceutical Establishments. Available from: https://uaelegislation.gov.ae/en/legislations/1426

Order of Implementation of the UAE Law (hereinafter – Resolution No. 90)[42]. Its Article 22 specifies the provision of a wide range of pharmaceutical and clinical consulting services both in technical and scientific terms. With regard to the qualification of pharmaceutical specialists, Article 6 of Decree No. 90 specifies the requirements for the necessity to undergo the admission procedure to perform pharmaceutical activities, and there is a reference to the relevant procedure. Subspecies of a pharmaceutical profession (activities) or pharmaceutical specialties are also defined by Unified Healthcare Professional Qualification Requirements[43] and Clause 5.2.2.9.1. of the DoH normative document[44,45]. Attention should be paid to the presence of provisions on "health care practitioners"[46] in the UAE Federal Law No. 6 dated May 31, 2023 "On the Employment of Certain Health Professions by Non-Medical and Pharmaceutical Professionals"[47]. The concept of "an authorized ("responsible") pharmaceutical specialist", a pharmacist responsible for the quality of pharmaceutical services provided by the PO, should be highlight separately, the information about it is included in the composition of the license for a pharmaceutical activity. The authors separately distinguish the concept of "an authorized ("responsible") pharmaceutical specialist", a pharmacist responsible for the quality of pharmaceutical services provided by the PO, information about which is included in the license for a pharmaceutical activity.

Drug compounding is a type of the performed work, the rendered services, constituting a pharmaceutical activity, which is established by subparagraph "b" of paragraph 1 – Article 22, paragraph 1 of Decree No. 90. According to the available data, drug compounding is performed in 32% of pharmacies in the UAE [34]. The provisions of the UAE Law divide POs into public and hospital ones, which refer to the collective concept of "a pharmaceutical institution".

To obtain a pharmaceutical license for both retail and drug compounding activities, a PO must comply with the technical and health conditions specified in UAE Ministerial Resolution No. (228) dated 13 October 2023, "Technical and health conditions for compounding pharmacies"[48] (hereinafter referred to as Resolution No. (228). Herewith, the director (head) of the compounding pharmacy must necessarily appoint a full-time pharmacist who has an appropriate authorization to carry out activities and, among other things, acts as a responsible pharmacist. The authors found that the pharmacies exclusively engaged in retail sales of registered MPs must meet certain sanitary and hygienic conditions set forth in the UAE Minister of Health and Prevention Decree No. 932, dated 2012, "On sanitary conditions to be observed in public pharmacies".

Regulation No. 228 establishes specialized definitions and concepts for the following pharmacies: "MPs traceability system" (requirements for the labeling of compounded MPs, which define the mandatory presence of a serial number or non-repeating symbols for each compounded MP, the date of compounding [month and year], an indication of the category of a compounded MP [individual – compounded by prescription or SP, a series number [batch], a composition, number of doses in the package, pharmacy details and a quality assurance analysis number [QAA] of the compounded MP); "A quality assurance system of a manufacturing pharmacy" (an internal system of requirements and rules developed and approved by each compounding pharmacy, compliant with current regulatory legal documents, which allow to ensure a proper quality of an implementation of all organization processes of the drug compounding activities, including activities on traceability after dispensing); "Record on starting and raw materials" (detailed information about the starting and raw materials in the CDPs, including sources of acquisition, and references to documented quality methodologies – a shelf life of any starting and raw material ingredient cannot be less than the "beyond-use date" – BUD of the CDPs); "MP Compounding Record" (documenting the fulfillment of technological processes); "Use-by date" (the date that the

[42] Cabinet Resolution Concerning the Executive Regulations of Federal Law Concerning Medical Products, Pharmacy Profession and Pharmaceutical Establishments. Available from: https://uaelegislation.gov.ae/en/legislations/1523

[43] Unified Healthcare Professional Qualification Requirements (PQR). Available from: https://www.doh.gov.ae/en/pqr

[44] Pharmacist and Pharmacy Technician Scope of Practice. Available from: https://www.doh.gov.ae/-/media/E160783B819C479D90E4DF8BAA108737.ashx

[45] Unified Healthcare Professional Qualification. 3rd Version, – 146, – 2022. Available from: https://www.dha.gov.ae/uploads/072022/Unified%20Healthcare%20Professional%20Qualification202273235.pdf

[46] Federal Law on the Practice of Some Medical Professions by Persons Other Than Physicians and Pharmacists. Available from: https://www.dha.gov.ae/uploads/092023/Federal%20Law%20no2023944635.pdf

[47] Renewal of a License to Practice as a Pharmacist. Available from: https://mohap.gov.ae/ar/services/renewal-of-a-license-to-practice-as-a-pharmacist

[48] Ministerial Resolution No. (228) of 2023 AD Technical and health conditions for the compound pharmacy, 28 Rabi ' al-awwal 1445h-13 October 2023. Available from: https://www.dha.gov.ae/uploads/102023/Ministerial%20Decision%20no2023107514.pdf

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compounding pharmacy sets for the compounded MP after which its use is prohibited – BUD), "Analysis (SOA)" (a certificate containing the results of a laboratory analysis of the compounded MP), "Pharmacy SOPs" (internal standards approved by the compounding pharmacy, which must not contradict an applicable law and which must be complied with by all employees of the compounding pharmacy; "Compounded drug product", "Annual Report", etc. For the last item, it should be specified that the report should contain information on each compounded MP: a composition of active substances and their concentration per unit; information on the starting and raw materials used; DF, dosage and route of administration; description of packaging; a number of units compounded or produced; a tracking identification code for each CDP; information on CDPs release (in case of release by prescription – patient data, a patient identification number, a copy of the prescription; in case of release at the request of a MO – a MO name, a copy of the contract for CDPs compounding services, a copy of the MO's request; information on the doctor and his license number; a report on a patient's medication treatment plan (upon a request) and patient information, including an identification number); information on the expiry date and period of the CDPs use; the date of release to the PO, a delivery to the PO, the time of the CDP receipt, including the time of the receipt affected by the time of compounding (which is significant for CDPs). The annual report must be submitted by the PO to the appropriate UAE Minister of Health and Prevention department not later than January 31 of the following year following the year during which the activity was performed and also upon a request by the licensing control authority.

The authors emphasize that a compounded drug product is an MP obtained (compounded or manufactured) by collecting or mixing raw materials, materials, or changing the qualitative or quantitative composition of active ingredients (in compounding) from FDFs, and dispensed by a compounding pharmacy for retail and wholesale sale for a domestic circulation to meet the needs of patients as prescribed by a physician or the needs of the MO in which it will be used, including dispensed raw materials in unprocessed (prepackaged mono-component doses) or partially processed. Resolution No. 228 specifies that hospital compounding pharmacies or POs belonging (by an ownership form) to public and private MOs are allowed to compound registered MPs ("to perform technological operations with registered MPs"). In this case, the composition of the compounded MP must *qualitatively* correspond to that stated in the registration certificate and subject to the prescription of such an MP in accordance with the indications for use established in the instructions for the medical use approved by the UAE Ministry of Health. In such cases, the hospital compounding pharmacy is required to obtain a UAE GMP certificate similar to that for MP manufacturers as stipulated in Article 23 of the UAE Law, including the requirements of Article 88 regarding quality management standards. The UAE GMP inspection and certification procedure is carried out by the MP Department of the UAE Ministry of Health. These provisions should be linked to the provisions of par. 1.4.2. part 1 of Resolution No. 228, which establishes a mechanism that allows the MO, in special cases and upon an approval of the authorized health authority, to enter into a service contract with a compounding PO for the production of pilot series of registered MPs intended for clinical trials of a "special nature", provided that the quality composition is maintained and the indications for the use of such MPs are consistent with the instructions for a medical use approved by the UAE Ministry of Health. In such cases, an executed contract between the MO and the compounding PO is required, as well as an application to the UAE competent health authority for the authorization (approval request). The application (request for approval) requires a justification of the reasons for the contract and a description of the cohort of patients for whom the therapeutic or pharmacoeconomic benefits are expected to be realized based on their treatment plan. In this case, the agreement made between the MO and the compounding PO should specify the mechanism and requirements for the transportation, shipping and storage of CDPs in accordance with the regulations governing these requirements. The authors believe that they are referring to the need to comply with the standards of good practice for storage, distribution, transportation and shipping (distribution) of MPs in the UAE, the Gulf Cooperation Countries, the procedure for issuing a Certificate of Compliance which is carried out by the UAE Ministry of Health and Prevention[49], in the manner prescribed by the UAE Minister of Health and

[49] Issue a Certificate of Compliance with the good Practice Standards of a Pharmaceutical Establishment. Available from: https://mohap.gov.ae/ar/services/issue-a-certificate-of-compliance-with-the-good-practice-standards-of-a-pharmaceutical-establishment

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Prevention Decree No. (22)[50] dated 15 February 2022. As required by Regulation No. 228, a compounding PO is responsible for the quality of CDPs and a MO is responsible for verifying the stability, safety and efficacy of CDPs. Thus, medical professionals who write a prescription or a request from the MO for CDPS share the responsibility with pharmaceutical professionals to ensure the safety of a dose selection and when taking the compounded MP, as well as in case of adverse reactions, effects or any symptomatic abnormalities in the patient, are obliged to inform the UAE Ministry of Health. It is considered, that this mechanism is particularly significant and promising for providing MPs to patients with rare (orphan) diseases.

Currently, compounding registered MPs is completely prohibited for registered pharmacies in the Russian Federation, and the "contractual" mechanism or model for determining MPs risk levels described in the previous paragraph, has not been implemented in the legislation. Although in compounding and dispensing under drug prescriptions of monocomponent CDPS containing monocomponent DSs without any excipients, which have undergone the procedure of grinding and in-pharmacy filling (e.g. streptocide powder, glucose powder, etc.), the standard prescription formulations of CDPSs do not contain any excipients (e.g. streptocide powder, glucose powder, etc.). in standard formulations "da tales doses numero"), as well as in case of dispensing according to the requirements of the MO of FDFs, which have undergone the procedure of intra-pharmacy filling (a procedure of breaking the primary packaging), the qualitative and quantitative composition of the registered MP does not change either.

It is important to pay attention to the technical conditions of p. 1.1.3. part 1. Decree No. 228, according to which compounding pharmacies may compound and dispense OTC MPs in the amount calculated according to the average monthly quantity of MPs manufactured according to doctors prescriptions and requirements of the Ministry of Health for the 3 previous months. The condition for compounding and dispensing of OTC CDPs (on a requirement of an individual) [18, 19] is also a due compliance with all technical and hygienic conditions of Decree No. 228 with fulfillment of requirements for dispensing of safe and quality CDPs within the established limit of MPs use (BUD). The same paragraph establishes the regulatory elements important from the point of view of a scientific exchange and increasing the availability of CDPs:

- compounding POs are prohibited from compounding formulations for which there is no scientific data or pharmacopoeial articles in the UAE approved pharmacopoeias according to Article 1(1) of the UAE Law;
- in addition, if the pharmacist is aware of the practice of another compounding PO with regard to the prescribed CDPs, it is acceptable to use the reference formulations of some other compounding PO, as well as those CDPs and DF formulations approved for use by the MO or public authority, provided that there is a signed non-disclosure agreement or contract between the compounding PO to disclose full information on the formulation, available regulations, CDPs and the necessary documentation for their compounding, quality control procedures, and the safety of use information, including the condition that these compounding POs have not been issued warning letters or restrictive measures by the competent health authority in the reference state of the UAE. With respect to this mechanism, according to Resolution No. 228, the UAE Ministry of Health reserves the right to determine the level of its responsibility for physical, territorial and price accessibility to provide safe and quality CDPs.

General requirements for compounding pharmacies are set forth in part 2 of Resolution No. 228; in addition to the above requirements, the key ones are:

- clause 2.4. indicates that compounding POs are prohibited to compound MPs in the form of transdermal therapeutic systems, MPs of the plant origin, dosed aerosols, as well as powder and dry mixtures for inhalation, except in cases where a deficiency or defect with regard to registered MPs is established;
- clause 2.8. specifies that all formulations (prescriptions) shall be manufactured in accordance with the requirements of the current pharmacopoeia and shall comply with PO quality assurance documents;
- clause 2.9. stipulates that the raw materials used in the drug compounding, shall be approved

[50] Ministerial Resolution No. (22) of 2022 AD regarding the regulation of the transportation, storage and distribution of medical products or raw materials used in their manufacture. Available from: https://www.dha.gov.ae/uploads/082022/Ministerial%20Decision%20no2022856380.pdf

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by the UAE authorized health authority, have a remaining shelf life of at least two thirds of the total shelf life, be subject to control at least once a year in an accredited laboratory;
– clause 2.18. defines storage conditions for raw materials and finished products, which must meet the requirements of the current pharmacopoeia or the manufacturer's instructions.

The chapter "General requirements" of Decree No. 228 to compounding POs defines the provisions that in order to perform pharmaceutical expertise of drug prescriptions and MOs requirements, verification of medical prescriptions, the manufacturing pharmacy is obliged to use current scientific literature, including information on active ingredients in the structure of documentation for registered MPs, reflecting the use of the data in the quality assurance system documents as a mechanism (regulation) of compounding POs. Also, the quality assurance system documents of compounding POs must also reflect the mechanism approved by the authorized ("responsible") pharmacist, providing for the recall of compounded MPs or CDPs series from the circulation in accordance with the pharmacovigilance guidelines approved by the UAE Ministry of Health.

Decree No. 228 consists of 9 parts with annexes, however, in its content part, it is not an independent GPHP of MPs compounding and dispensing, it determines general requirements and technical conditions for the implementation of MPs compounding activities. The authors came to the conclusion that, from the point of view of norms in the organization of pharmaceutical activities with the right to compound MPs, the above-mentioned system is partly comparable to the approaches in the current Russian legislation, where Order No. 647 applies exclusively to the retail sale of MPs and ignores the peculiarities of MPs compounding activities in POs. Herewith, the main provisions and design of UAE Order No. 228 are highly comparable to the current Russian Rules for Manufacturing and Dispensing MPs[51], except for certain provisions allowing POs to compound registered MPs while complying with GMP requirements. Thus, this model of regulation of compounding POs in the UAE is highly comparable to the model implemented in the USA.

[51] Order No. 249n of the Ministry of Health of the Russian Federation dated 22 May 2023 "On Approval of the Rules for the manufacture and release of medicines for medical use by pharmacy organizations licensed for pharmaceutical activities". Available from: https://docs.cntd.ru/document/1301699481

### South Africa

Pharmacy compounding of MPs in Republic of South Africa is governed by the Medicines and Related Substances Act of South Africa No. 101 dated 1965[52], where the activities of POs must comply with the Pharmacy Organizations Act of South Africa No. 53 dated 1974[53] [35]. Based its provisions, all pharmacists and POs must comply with the South African Good Pharmacy Practice Regulations (hereinafter referred to as the South African GPHP)[54].

The South African GPHP in its preamble harmonizes with the European Union's concept of pharmaceutical care as a set of pharmaceutical services, and also exposes the role of pharmaceutical specialists in the South Africa public health.

In general, the South African GPHP is a comprehensive document dealing with all aspects of POs pharmacy operations, including quality assurance system requirements, and in relation to compounding pharmacies, the document contains the following sections with their own peculiarities:

1. Compounding all types of sterile DFs:
   – in compliance with GMP requirements for compounding sterile MPs;
   – with the possibility of a retrospective microbiological CDPs control.
2. Reconstitution (dilution) of non-toxic parenteral DFs:
   – when a laminar flow cabinet is available.
3. Compounding and reconstitution (dilution) of parenteral cytostatics:
   – with at least a Class 2 biosafety box and uniformity of regulations for POs and MOs;
   – with compliance with protective clothing and proper cleaning requirements;
   – with additional toxic substance training for the staff.
4. Compounding of non-sterile drugs:
   – at a minimum, under the supervision of a pharmacist;
5. Intra-pharmacy packaging of registered MPs:
   – in compliance with GMP regulations, in terms of primary MPs packaging, and Good Distribution Practice regulations, according to storage and transportation requirements.

[52] Medicines and Related Substances Act 1965. Available from: https://www.saflii.org/za/legis/consol_act/marsa1965280/
[53] Pharmacy Act 1974. Available from: https://www.saflii.org/za/legis/consol_act/pa197498/
[54] Rules relating to good pharmacy practice. Available from: https://www.saflii.org/za/legis/consol_reg/rrtgpp362/

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In accordance with the South African GPHP, compounding of RFLPs in POs is carried out in accordance with the GMP requirements for the production of radiopharmaceutical MPs and sterile MPs.

The described system of normative legal regulation of MPs compounding activities is comparable to that in the USA [16, 17].

### Ethiopia

In reviewing the regulatory framework for MPs compounding in Ethiopia, it should be noted that its health governance structure is based on the North American experience of the public administration, both in terms of the existence of a single mega-regulator with a similar name (Ethiopian Food and Drug Authority) and the publication of explanatory documents in the form of guidelines [16, 36].

In Ethiopia, the circulation of MPs is regulated by Proclamation No. 1112 dated 28 February 2019[55], and according to Article 34, of which compounding of MPs is carried out from drugs. Despite the fact that according to the text of the proclamation there is no prohibition on compounding parenteral drugs, the authors of this study were not able to identify any legal acts regulating this type of activity, which can also be traced from the data of scientific publications on pharmacy MPs compounding in Ethiopia [37–40].

However, in 2022, the now defunct Ethiopian MPs Control Authority issued Good Practice Guidelines on compounding[56]. In its introductory part, it declared that compounding MPs in the form of DFs for a local use was a common practice of POs and MOs. For the latter, the document fragmentarily increased the requirements for the necessary quality assurance system, premises, labeling, personnel, equipment, documentation, raw materials.

In 2020, the Ministry of Health of Ethiopia issued three-chapter National Guidelines for the Administration of Dermatological MPs[57], which also applies to POs and MOs. The first chapter describes the background of the document, the second chapter is devoted to the direct regulation of MPs compounding activities and is a direct translation of the provisions of the US Pharmacopeia for non-sterile DFs (503A type pharmacies) [16, 17], the third chapter contains a list of dermatologic CDPs formulations with a composition and suggested methodology for their compounding.

The authors of this study were unable to ascertain from available sources of information the availability of the infrastructure and regulations for radiopharmaceutical MPs compounding activities in Ethiopia.

### Iran

In Iran, the main regulator of the pharmaceutical market and MPs circulation is the Ministry of Health and Medical Education (hereinafter – the Ministry of Health of Iran), its executive bodies are: Food and Drug Administration of Iran (hereinafter referred to as IFDA) and the Supreme Council of Health Insurance (SCoHI) [41]. According to the latest IFDA statistics, there are about 11 036 functioning pharmacies in Iran, 10,028 of which are public pharmacies and the rest are hospital pharmacies[58].

Pharmaceutical legal framework in Iran is divided into 5 separate levels: constitutional; long- and medium-range planning, including relevant legislation; pharmaceutical legislation; subordinate regulations; international rules and agreements [42]. The general elements of the MPs regulation system of MPs circulation of Iran, relevant for the purpose of this study, are:

1. According to Article 3 of the Iranian Law on Medical, Pharmaceutical, Food and Drinking Products (hereinafter referred to as the Iranian Law) and subsequent amendments, import, export, sale and purchase of MPs without obtaining a license from the Iranian Ministry of Health are prohibited, Ch. 4 defines the requirements for the production and import.
2. IFDA exercises the authority to register MPs and maintains the relevant state register[59].
3. In a certain part it can be said that the analog of the list of Vital and Essential Drugs of the Russian Federation is the List of Iranian Medicines (hereinafter – IML)[60], which is formed and revised by the Iranian Drug Selection Committee (IDSC), which is a part of IFDA and has pharmaceutical specialists [43].
4. Iranian law restricts the production, import,

[55] Proclamation No. 1112/2019. Available from: http://www.fmhaca.gov.et/wp-content/uploads/2020/06/Food-and-Medicine-Administration-Proclamation-1112.pdf

[56] Good Pharmaceutical Compounding Laboratories. Available from: https://www.ethiopianreview.com/pdf/001/Labcomp.pdf

[57] Ministry of Health-Ethiopia. National guideline for compounding of dermatological preparations; 2020.

[58] Ministry of Health. The Food and Drug Administration. The business of pharmacies; 2018. Available from: https://www.fda.gov.ir/

[59] IFDA. Available from: https://www.fda.gov.ir/ورود-هرادا-ی‌اه-ک‌نی‌ل/روش‌ک-ی‌ی‌ورود-ی‌م‌س‌ر-ت‌س‌رهف

[60] Ibid.

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distribution and prescribing MPs not included in the IML, while there is a mechanism under Iran's Emergency Pharmaceutical Care Centers (EPC) Law to provide MPs not included in the IML in cases of shortage (deficiency) of approved MPs or for the treatment of patients with life-threatening conditions. In such cases, Art. 2 of the Law stipulates that the physician and the patient must sign a consent that they understand the risk of possible lack of efficacy in the use of such MPs and (or) the occurrence of a certain amount of side effects.

5. In addition to the retail markup for MPs, POs of Iran are authorized to impose a surcharge for MPs vacation[61];
6. Based on the Iranian Law on Supply of Medicines, in case of lack of interest from the private sector to invest and open POs in remote and disadvantaged areas, the Iranian Ministry of Health is obliged to provide relevant MPs through subordinate MOs to ensure the availability of MPs.
7. Iran has not acceded to the WTO and has not signed the Agreement on Trade-Related Aspects of Intellectual Property Rights [44], but has accepted the World Intellectual Property Organization agreement and adopted the Law on Patents, Industrial Designs and Trademark Registration[62].

According to the Iranian Law, a pharmacy is a health care institution that dispenses MPs and provides various pharmaceutical services to the public. According to Article 2 of the above law, the fulfillment of all regulatory requirements imposed on POs should be supervised only by the responsible official (pharmacist).

According to Article 4 of the Iranian Pharmacy Law (hereinafter referred to as the Iranian Pharmacy Law) [42], the types of services of community pharmacies are specified, and each qualified pharmaceutical specialist is allowed to obtain only one pharmacy license. Unqualified pharmaceutical personnel ("pharmacy technicians") are included in the pharmaceutical specialists, in respect of whom the legislation does not establish any requirements on the need to complete pharmaceutical education programs and (or) obtain admission to pharmaceutical activities, while unqualified pharmaceutical personnel are trained directly on the job. The duration of higher pharmaceutical education programs is 5.5 years[63].

The Iranian Pharmacy Law defines restrictions on the maximum possible number of pharmacies based on the number of urban or rural population.

The duties of a pharmacist are set out in Article 25 of the Iranian Pharmacy Law, which includes: performing technological operations for in-pharmacy packaging of MPs; compounding and dispensing MPs, including galenic ones.

In addition, Article 33 of the Iranian Pharmacy Law defines the minimum areas for POs, including 24-hour POs, as well as storage conditions.

The authorse have established the studies in which various Iranian authors have repeatedly noted the problems of the need to improve the level of safety and health protection of medical and pharmaceutical specialists involved in the compounding of MPs. It is also necessary to note the problem of the negative impact of cytotoxic MPs on the medical personnel in the implementation of activities for the recovery (dilution) of MPs and the lack of specialized POs that would carry out the compounding of MPs from highly toxic and hazardous substances [45, 46]. The authors note significant technical availability limitations of the open sources and regulatory legal documentation of Iran on the issue under study, difficulties in translation from Persian (Farsi) [47], an insufficient level of the representation in the public domain of regulatory legal documents of the Ministry of Health of Iran and IFDA, including blocking an access to a number of resources on the Internet, also through virtual private networks (VPNs). At the same time, a relevant study [48] was analyzed, which shows the experience of Iranian pharmacists in establishing the first compounding pharmacy under the Ministry of Health of Iran for the drug compounding that meets the GMP principles, as well as Chapters 797 and 800 of the US Pharmacopeia. The paper describes the main stages of creating a modern, high-tech pharmacy infrastructure, including a construction of clean premises, adopted approaches to the human resource management, building process principles of a quality assurance and a quality control system, the development and SOPs implementation,

[61] Principles notified by the Food and Drug Organization under No. 57412/655 dated 17/06/2019 «Notification of instructions on how to obtain the tariff for pharmaceutical services in the year 1400». Available from: https://arakmu.ac.ir/vcfd/fa/news/18004/هفرعت-زاسوراد-لاعف-روضح-رب-یدج-تراظن-م وزل-هناخوراد-رد-یئوراد-تامدخ هناخوراد-رد-ینف-لویئسم

[62] Patents, Industrial Designs and Trademarks Registration Act. Available from: http://www.wipo.int/wipolex/en/details.jsp?id=7706

[63] Pharmacy Education and Regulations in Iran. Available from: https://irimc.org/en/Regulations/Pharmacy-Education

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the documentation and automation processes. The study refers to two standards (not available in the public domain) that govern clean premises specifications for cytotoxic MPs compounding, established requirements to locate the facilities either within a hospital pharmacy structure or in a close proximity to an injectable MPs administration unit for chemotherapy (a centralized MPs dilution (reconstitution) room as a part of a medical license [16]). In addition, the article postulates the existence of guidelines for the management of chemotherapy services adopted by the Iranian Ministry of Health, which stipulate the need for such an infrastructure in every MO that has anti-tumor drug therapy (chemotherapy) departments with 12 or more beds.

In the Russian-language literature, the presence of a study of the pharmaceutical sector in Iran, which reflects the standing and prospects of the market, but is also limited to references to primary sources of the regulatory framework, was found [49]. The work devoted to the peculiarities of introducing Russian pharmaceutical products to the Iranian market and based on the practical experience, which also concluded that it is necessary to conduct a comprehensive and sufficiently deep study and the analysis of political, socio-cultural, economic, regulatory and legal aspects of business activities in Iran, is of particular interest[64].

### Egypt

The Egyptian Drug Authority (EDA)[65] is the national regulatory authority for MPs. The EDA reports directly to the Prime Minister[66] and its activities are supervised by the Ministry of Health and Population of Egypt (Ministry of Health and Population). The functional structure of the EDA includes three independent organizations:

1. The Central Administration for Pharmaceutical Affairs (CAPA), which covers the registration, pricing, regulation of promotion and/or advertising of MPs, as well as control and supervision functions of participants in the sphere of the drug circulation.
2. The National Organization for Drug Control and Research (NODCR), responsible for the quality control of circulating pharmaceutical products, cosmetics, medicinal plants, insecticides, raw materials and products of the natural origin.
3. The National Organization for Research and Control of Biologicals (NORCB), which carries out the procedures for authorizing the sale (trade, dispensing) and licensing of various professional activities.

It can be said that for the Egypt's pharmaceutical regulatory system, the national regulatory authority for MPs is the specialized body of the African Union – the African Medicines Agency (AMA)[67,68] whose objectives include the development and support of a harmonized regulatory framework, the development of the pharmaceutical industry, including MPs, traditional medicines and medical devices, including the ones within the framework of the African Continental Free Trade Area ("Africa Continental Free Trade Area" AfCFTA).

Egypt's main legislative documents in the sphere of circulation of medicines include the following:

1. Law No. 127 dated 10 March 1955 on Pharmaceutical Activities (hereinafter referred to as Egyptian Law No. 127)[69,70].
2. Law No. 15 dated 5 March 2017 "On simplifying the procedure for issuing licenses to industrial facilities"[71].
3. Resolution of the Minister of Industry and Trade No. 1082 dated 16 August 2017. "On the implementing regulations to Law No. 15 dated 5 March 2017. "On Simplifying the Procedure for Issuing Licenses to Industrial Facilities"[72].

[64] Tsatsyn N. Features of the introduction of pharmaceutical products to the Iranian market (from practical experience). In: GxP News. Available from: https://gxpnews.net/2019/10/osobennosti-vyvoda-farmacevticheskoj-produkcii-na-rynok-irana-iz-prakticheskogo-opyta/?ysclid=m1m9k8z262569120004

[65] Law No. 101 of 1971 on Medicine, Medical Technology Management and the Egyptian Drug Authority (with changes at 25.08.2019). Available from: https://edaegypt.gov.eg/media/52vavp5k/2019-151.pdf

[66] Prime Ministerial Resolution No. 777 of 2020 Issuing the executive regulations of the law establishing the Egyptian Authority for Unified Procurement, Supply, Medical Agents, Medical Technology Management and the Egyptian Drug Authority. Issued by Law No. 101 of 1971. Available from: https://edaegypt.gov.eg/media/es5a1awn/قرار-رئيس-مجلس-الوزراء-رقم-777-لسنة-2020-بإصدار-اللائحة-التنفيذية.pdf

[67] Treaty for the Establishment of the African Medicines Agency. Available from: https://au.int/sites/default/files/treaties/36892-treaty-0069_-_ama_treaty_e.pdf

[68] The Treaty on the Establishment of the African Medicines Agency was adopted at the 38th ordinary session of the Assembly of the African Union on 11 February 2019, which entered into force on 5 November 2021 (currently 38 of the 55 member States of the African Union have signed and/or ratified the said treaty). Russian

[69] Egyptian Pharmacy Practice Law Number 127. Available from: https://edaegypt.gov.eg/media/v0wfy2bk/1955-127.pdf

[70] Amendments to Law No. 127 of 1955. Available from: https://edaegypt.gov.eg/ar/القوانين-واللوائح-التنفيذية-لقانون-رقم-127-لسنة-1955/

[71] Law No. 10 of 2017 Issuing the Law to Facilitate Procedures for Granting Industrial Establishments Licenses. Available from: https://edaegypt.gov.eg/media/4t1j33qb/2017-15.pdf

[72] Ministry of Commerce and Industry Decision No. 1082 of 2017 issuing the executive regulations of the law regulating the procedures for the inspection of hazardous materials issued by Law No. 15 of 2017. Available from: https://edaegypt.gov.eg/media/zs4ja0ex/2017-1082.pdf

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4. Other laws regulating the clinical trials, operating procedures, collection of blood and plasma for the production and export.

The key subordinate regulatory legal documents in the field of organization of pharmaceutical activities with the right to compound MPs include:

– Ministerial Decree No. 265 dated 16 April 1981 "On sanitary and technical requirements to be observed in pharmaceutical enterprises"[73];
– Ministerial Decision No. 25 dated 18 January 2009 "On requirements for the licensing of pharmacies"[74];
– Ministerial Decision No. 114 dated 3 February 2017 "Regarding union certificates required in the licensing of public pharmacies"[75];
– Decision of the Chairman of the Authority No. 271 dated 25 May 2021 "Regarding the conditions to be observed in pharmacy organizations"[76];
– Decision No. 265 dated 21 May 2024 of the President of the Authority "On issuing a methodological guide on the mechanisms, procedures for verifying and monitoring the implementation of the correction plan submitted by stores, warehouses and pharmacies"[77].

According to the Egyptian Pharmacists Syndicate (EPS), the total number of community pharmacies in Egypt had reached the figure of 95 000 by the end of 2023. Herewith, the number of pharmacists reached 313 000, up from 175 000 in 2013 and 71 000 in 2003. Egyptian Law No. 127 stipulates that public pharmacies in Egypt (dispensing only FDFs) can operate not only with pharmacists, but also with other non-regulated pharmacy personnel, which includes their assistants who have neither medical nor pharmaceutical education. Although the law restricts the formation of pharmacy networks, the provisions on "pharmacy management" allow a pharmacy technician to manage a group of pharmacies, thus forming pharmacy networks [50].

There is a significant number of regulatory documents[78] for Egyptian POs that reflect modern approaches in the organization of MPs compounding activities. In particular, compounding pharmacies are subject to the regulations of the "Egyptian Guidelines for Oncology Pharmacy Practice" (EGOPP) in the format of good manufacturing practice for MPs used for the treatment of cancer. The guidelines consist of 2 volumes[79].

"MPs compounding" refers to the process by which unit operation steps are carried out to produce the MPs suitable for use by the patient.

The first volume contains "Guidelines for the Manufacture of Sterile MPs, Non-sterile MPs and Safe Handling of Highly Active (Hazardous) Substances". Its content and provisions directly refer to the regulatory requirements of the US Pharmacopeia, Chapters 795, 797 and 800 [16, 17].

Sterile MPs made from non-hazardous substances include: parenteral nutrition, hydration protocols, chemotherapy premedication, and antibiotics.

For sterile MPs made from hazardous substances, the Guidelines include: antineoplastic drugs; any drugs identified in the "List of Antineoplastic and Other Hazardous Drugs in Health Care Settings," compiled by the National Institute for Occupational Safety and Health (NIOSH)[80,81].

The minimum requirements for the facilities and quality assurance system of a compounding pharmacy are presented in Chapter 3 of the Guidelines.

For non-sterile MPs, the Guidelines include topical MPs for the extravasation and MPs used for oral mucositis caused by chemotherapy and/or radiotherapy.

In a separate volume, there are "Guidelines for compounding biological MPs and biosimilars"[82].

[73] Ministerial Decree No. 265 of 16/04/1981 on the health and technical requirements to be met in pharmaceutical factories. Available from: https://edaegypt.gov.eg/media/0flb3fyk/1981-265.pdf

[74] Ministerial Decision No. 25 of 18/01/2009 On the requirements required for licensing pharmaceutical stores. Available from: https://edaegypt.gov.eg/media/cw5ozyh4/2009-25.pdf

[75] Regarding the Union certificates required during the licensing of public pharmaciesministerial Decision No. 114 of 02/03/2017. Available from: https://edaegypt.gov.eg/media/xrek4hlt/2017-114.pdf

[76] Decisions of the Ministry of Health and population decision no. 271 of 25/05/2021. Available from: https://edaegypt.gov.eg/media/قرارئيس-الهيئة-قرم-271-2021.pdf

[77] Guidelines for File Assessment for Pharmaceutical Products for Human Use. Available from: https://edaegypt.gov.eg/media/zpidyytc/guidelines-for-file-assessment-for-human-pharmaceutical-product.pdf

[78] Regulatory evidence. Central Pharmaceutical Care Administration Guidelines. Available from: https://www.edaegypt.gov.eg/ar/القطاعات-والإدارات-المركزية-للرعاية-الصيدلية-الإرشادات-والبروتوكولات-الخاصة-بإدارة-الرعاية-الصيدلية-في-المستشفيات

[79] Egyptian Guide for Oncology Pharmacy Practice. Available from: https://edaegypt.gov.eg/media/hrqcj435/edrexgl-cap-care-011-egyptian-guide-for-oncology-pharmacy-practice-volume-1-2022-2.pdf

[80] NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. Available from: https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

[81] Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020; Procedures; and Risk Management Information. Available from: https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

[82] Egyptian Guide for Oncology Pharmacy Practice. Available from: https://edaegypt.gov.eg/media/vkvbbcmd/eda-guide-for-oncologu-pharmacy-practice-vol-2-biosimilars-chapter_1.pdf

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## CONCLUSION

For the first time, this study presents generalized materials on the main regulatory approaches and requirements for the implementation of activities in the field of MPs compounding applied in the regulatory systems of the BRICS interstate association (Union) member countries. This study has no analogues in domestic and foreign literature. The study presents key regulatory legal acts and documents, analyzes them and describes the main provisions of the legal framework for organizing the activities of compounding pharmacies. The results of the study determine the need to rethink the current state of the Russian regulation of MPs compounding. The work emphasizes the need for the development and implementation of a single, harmonized good practice of MPs compounding and dispensing, applicable to any of the types of compounded MPs, the FD type, the intra-pharmacy filling and reconstitution (dilution) of registered MPs both within pharmaceutical and medical activities, including in the format of " hospital exemptions". The implementation of the only currently missing element of the good practices system is particularly important in achieving the national health care development goals established in the Russian Federation in accordance with the project "New Health Saving Technologies", a transition to modern, advanced practices of mastering critical technologies, personalized, predictive and preventive medicine, high-tech health care and health saving technologies, including the ones through the rational use of MPs, the use of genetic and genetic technologies, the use of genetic data and technologies, mastering the compounding of biomedical cellular products and tissue engineering products, which are of high interest for medical and pharmaceutical science.

In the sphere of MPs compounding, the BRICS countries can strive to develop the best practices and "gold" standards for the organization of relevant socially important activities, regulation and accessibility of CDPs. The principle of the BRICS alliance does not initially impose on its members one or another way of the state governance and normative legal regulation, but seeks to improve the quality and living standard of the member countries citizens.

In this sense, there is no need for total the harmonization or unification of activities regulation in the field of MPs compounding, but it makes sense to study the best practices in this area in the BRICS countries, to highlight and implement them, and for the BRICS governance bodies to strive to achieve high indicators of the member countries of the association: organization, regulation, accessibility, innovativeness of CDPs. This approach could lead to the creation of a single GPHP, but does not require it at the moment due to the need to focus on the main parameters of MPs circulation. The study of the best practices and development of "gold" standards can become the task of a world-class scientific center. Such practices and standards may include the following:

– Brazilian experience of using scientific literature in the absence of the necessary pharmacopoeial monograph, as well as the POs right to independently develop necessary specifications for raw materials, quality control methodologies on CDPs;
– experience of India, when the Central Government of India forms the Pharmaceutical Council;
– UAE's experience, which allows the compounding of registered MPs only in cases where no change in their qualitative composition is carried out;
– quantitative indicators of an availability of CDPs to the residents of the country, etc.

Given the fact that by now, there is information about the interest of additional 34 countries in the activities of the association (the creation of BRICS partner states is being discussed), the Russian Federation, which is chairing BRICS this year, faces the task of facilitating the fastest possible integration of the new member countries into all mechanisms of the association. From the point of view of improving the interaction efficiency between representatives of the BRICS countries in the healthcare and pharmaceutical industries, the authors note the presence of national medical research centers and world-class scientific centers established and operating in Russia, created in accordance with the Decree of the President of the Russian Federation No. 939 dated 22 June 1993 and p. 2, art. 5 of Federal Law No. 127-FZ dated 23 August 1996. Their activities, in accordance with the priorities of scientific and technological development of the Russian Federation and the directions of development of the most important science-intensive technologies provided for by the Decree of the President of the Russian Federation No. 529 dated 18 June 2024, are aimed at research and development in the field of preventive and personalized medicine, ensuring healthy longevity, development of high-tech healthcare, health-saving technologies, and MPs. It is also possible to initiate the process of creating a World-Class Scientific and Educational Center in the field of drugs manufacturing, organized on the basis of integration of higher education institutions, scientific organizations and their cooperation with organizations who's operating in the real sector of the economy. In

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general, as for the BRICS member countries, the results of this study necessitate a further in-depth elaboration of the convergence issues of regulatory practices of both health care systems and pharmaceutical industries including clinical trials, MPs inspection and registration, the MPs production and compounding, including radiochemistry and radiation safety.

Another promising direction of the interaction is the pharmacopoeias requirements harmonization of the member countries association – it is an exchange of experience in the CDPs compounding and the nomenclature analysis of the most demanded for CDPs compounding between the member countries, which will also contribute to ensuring the uniformity of approaches and requirements to the quality of the MPs compounded in pharmacies. In line with the goals and objectives of the Concept of Russia's Participation in BRICS, the results of this study raise the question of the need to develop and form a "Roadmap (an action plan) for the development of the interaction between the BRICS member states in the field of health care and the pharmaceutical industry", which could become the basis for the establishment (expansion of existing centers) in the form of a national pharmaceutical research center or a world-class scientific center in order to perform the functions of promoting the most rapid integration and building a modern model of the common MPs market, joint research and development for technological development of the interstate association (Union) countries. The implementation of the above proposals is aimed at achieving the national goals established in the Decree of the President of the Russian Federation dated 07 May 2024 № 309, and their consideration is recommended to the Government of the Russian Federation in the formation of the "Unified plan to achieve the national development goals of the Russian Federation for the period up to 2030 and in the perspective up to 2036".

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All the authors have made equivalent and equal contributions to the publication. All the authors confirm that their authorship meets the ICMJE international criteria (all the authors have made substantial contributions to the conceptualization, research and preparation of the article, and have read and approved of the final version before the publication).

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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## AUTHORS

**Dmitry S. Yurochkin** – Deputy Head of Laboratory of Regulatory Relations and Good Practices of St. Petersburg State Chemical and Pharmaceutical University. ORCID ID: 0000-0003-4609-0155. E-mail: dmitry.yurochkin@pharminnotech.com

**Devi D. Mamedov** – junior researcher of

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Laboratory of Regulatory Relations and Good Practices of St. Petersburg State Chemical and Pharmaceutical University. ORCID ID: 0000-0001-5061-0729. E-mail: devi.mamedov@mail.ru

**Sergey E. Erdni-Garyaev** – Senior Lecturer at the Department of Physical and Inorganic Chemistry, St. Petersburg State Chemical and Pharmaceutical University. ORCID ID: 0000-0001-6297-9304. E-mail: sergey.erdny-garyaev@pharminnotech.com

**Aleksei V. Yarutkin** – Deputy Director of the Institute of Pharmacopoeia and Medicinal Product Standardisation of Scientific Center for Evaluation of Medical Products. ORCID ID: 0000-0002-3156-5958. E-mail: yarutkin@expmed.ru

**Valeria L. Bagirova** – Doctor of Sciences (Pharmacy), Professor, Director of the Institute of Pharmacopoeia and Medicinal Product Standardization of Scientific Center for Evaluation of Medical Products. ORCID ID: 0000-0003-0379-6158. E-mail: bagirova@expmed.ru

**Pavel S. Guryanov** – Candidate of Sciences (Pharmacy), Deputy Dean of the Faculty of Training of Foreign Citizens of Perm State Pharmaceutical Academy. ORCID 0000-0003-0275-9937. E-mail: laboratory.iot@gmail.com

**Omar Loudiyi** – student of Perm State Pharmaceutical Academy. ORCID ID: 0009-0009-3768-4315. E-mail: omarloud1008@gmail.com

**Li Wen** – independent researcher, Beijing, China. ORCID ID: 0009-0000-2770-1868. E-mail: wen890425@outlook.com