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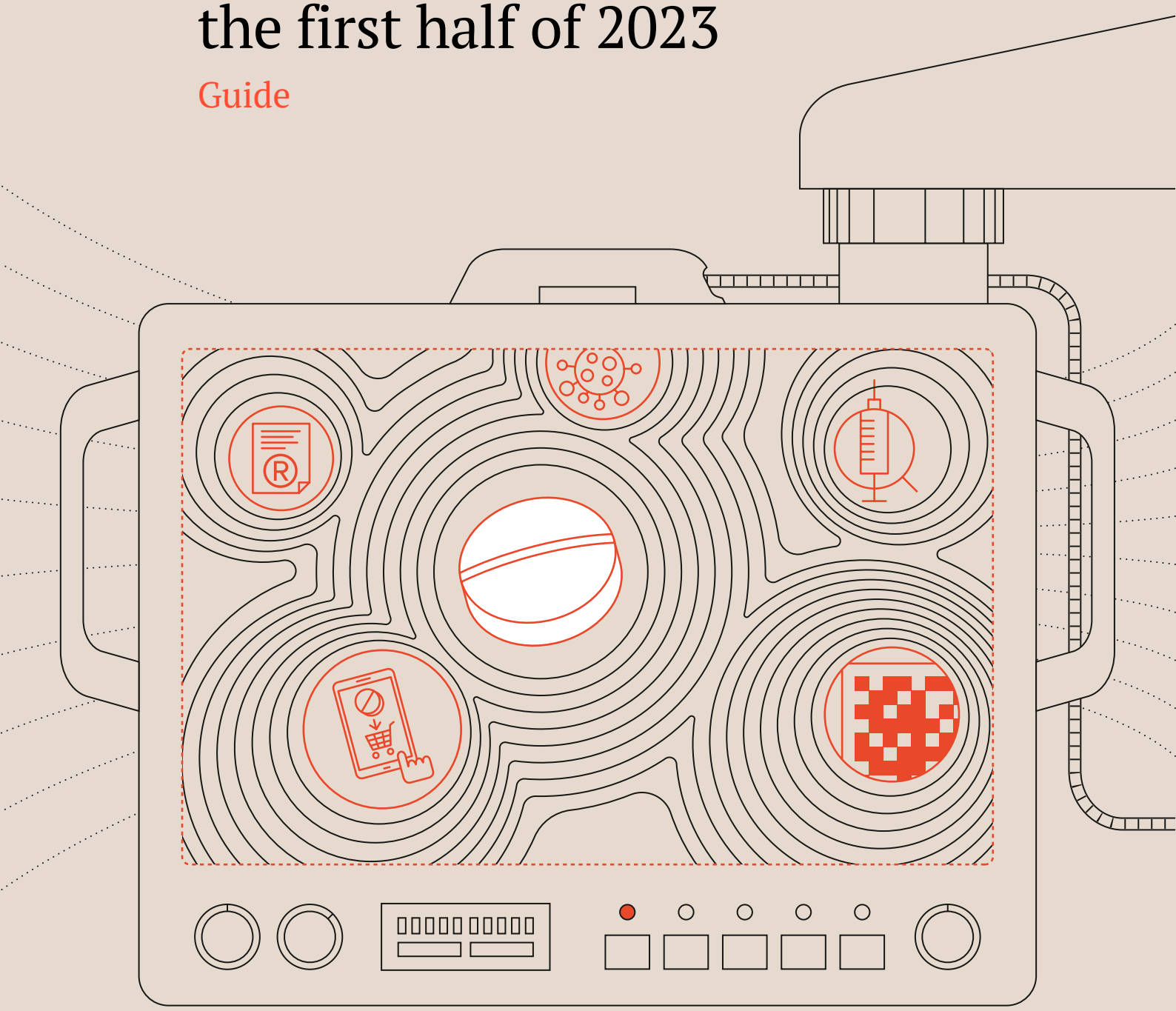
Legal updates in the Russian Life Sciences industry for the first half of 2023

Guide



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Launch of an experiment to sell Rx medicines online

In Russia, certain types of products could not be sold online, including medicines, until the global COVID-19 pandemic pushed the Russian government to allow the distribution of over-the-counter (OTC) medicines via e-commerce platforms in 2020. Discussions on the feasibility of safe online sales of Rx medicines continued until autumn last year when Russia adopted an experimental law on online sales of Rx medicines[1].

The law launched a pilot project, whereby online sales are restricted both in terms of the geography, timeframe and variety of medicines. Rx medicines may be sold online only in Moscow, the Belgorod Region and the Moscow Region. The experiment kicked off on 1 March 2023 and will continue until 1 March 2026.

The list of Rx medicines allowed for online purchase includes more than 1,000 medicines, including drugs for the treatment of diabetes, HIV, Hepatitis C, cancer and oncohematological diseases, and musculoskeletal disorders. Remote sales of medicines containing narcotic, psychotropic or potent substances, alcohol-containing medicines with an ethyl alcohol fraction over 25 percent, immunobiological medicines stored below a temperature of 15 degrees Celsius, medicines produced in pharmacies and medicines dispensed free of charge or at a discount for citizens who have the right to receive them at the expense of the budget are prohibited.

Dietary supplements will be additionally regulated at the EAEU level

The Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing has proposed amending the Technical Regulations of the Customs Union "On the Safety of Food Products" (TR TS 021/2011) and "On the Safety of Certain Types of Specialised Food Products, including Therapeutic and Preventive Dietetic Food Products" (TR TS 027/2012) in order to change the special requirements for dietary supplements (NS) and their production, sale and labelling. In particular, the amendments to TR TS 021/2011 aim to clarify terminology in the definition of the term "dietary supplement", the specifications of the permissible composition of the ingredients, the source of origin of dietary supplements and the mandatory release of the dosage form.

The corresponding draft decision of the Council of the Eurasian Economic Commission is undergoing a public discussion and anti-corruption expert examination. If adopted, products containing dietary supplements will be classified as specialised food products and regulated accordingly by the technical regulations of TR CU 027/2012.

In addition to the regulation of dietary supplements, there is also a proposal to amend and clarify the approach to the definition of food for athletes, food for diabetics and the concept of gluten-free and low-gluten products.

1. Federal Law No. 405-FZ dated 20 October 2022 on Amendments to the Federal Law on the Circulation of Medicines.

The government extended the moratorium on scheduled business inspections

A year ago, Decree No. 336 of the Russian Government dated 10 March 2022 established a moratorium on scheduled business inspections until the end of 2022. On 10 March 2023, the Russian government adopted Decree No. 372 extending said moratorium until 2030.

Clarifications were also made to certain grounds for conducting unscheduled inspections as part of state control as well as exercising state control (supervision) over the activities of the state and local authorities of Russia's regions. Now they will be conducted in the event there is a risk of a violation of mandatory requirements.

In addition, facilities with extremely high and high risk categories will be inspected, such as social and industrial facilities and certain activities with a maximum or close to maximum risk of causing harm in a particular area. For these facilities, the control authorities will conduct inspections based on special indicators. As the Russian government explained, the use of such indicators implies that the supervisory bodies will initiate control measures if they become aware of risks of a violation of mandatory requirements.

An experiment on a track-and-trace system for medical devices has been extended

Decree No. 322 of the Russian Government dated 28 February 2023 extended an experiment for the labelling of certain types of medical devices with track and trace marks by six months until 31 August 2023. There are six types of medical devices involved in the experiment: hygiene products, CT scanners, coronary stents, hearing aids, orthopaedic shoes, and air disinfection purifiers.

During the experiment, its participants (on a voluntary basis) tested the methods used to apply means of identification, aggregate labelled goods in a transport box and pallet, transfer information on labelled goods via an electronic document flow, and withdraw medical devices from circulation with the use of cash register equipment.

The experiment was previously expected to end on 28 February 2023. The decision to extend the experiment was taken in December at a meeting of the State Commission on Combatting Illicit Trafficking in Industrial Products. The extension was granted because the specifics of the circulation of medical products require additional study in terms of both regulations and the functionality of the information system.

Maximum fee to be established for marketing and promotion services

The deputies of the Russian State Duma have proposed limiting the maximum fee for pharmaceutical promotion services to 5% of the price. They noted that similar restrictions already exist for food products and dietary supplements, but the fee for such services can be set at one's own discretion with respect to pharmaceuticals.

The authors of the initiative point out that since the end of February 2022 the amount of fees for services to promote medicinal products at pharmacy chains has increased manifold. In some cases, it has reached 30% and occupied a significant share of the total revenue of pharmacy chains. The deputies believe that additional remuneration to pharmacy chains for the promotion of medicines makes it difficult for manufacturers to finance new and innovative medicines, conduct clinical trials and modernize production sites. This leads to defects and difficulties in import substitution and increases the cost of drugs for consumers.

It is not the first attempt to limit costs associated with marketing and promotion services: a similar proposal was introduced in 2020. At that time, the bill was introduced to ensure that consumers have sufficient medicines and stable access to it. The previous version proposed limiting the pharmacy chains' maximum market share to 20% and the amount of payments under marketing contracts to 5%. However, the bill has faced significant resistance from both the government and the pharmacy business.

In February 2023, deputies said they were ready to revisit the issue in the spring. Alexander Petrov, a member of the State Duma Committee on Health Protection, said the respective draft law had been previously rejected based on the prudence of pharmacies. However, the situation has not improved recently and there is significant tension in this regard between pharmacy chains and pharmaceutical manufacturers.

Simplification of registration procedure for veterinary medicines

Russian President Vladimir Putin has signed a law to simplify the procedure for the state registration of human drugs as veterinary medicines, which will come into force on 1 September 2023.

The new rules introduce a simplified procedure for the state registration of veterinary medicines for pets if such medicines have already been registered for the treatment of people. Such medicinal products will undergo an accelerated state expert examination procedure: the results of pre-clinical studies for use of the medicinal product in the treatment of humans can be submitted for state registration as a veterinary medicinal product. In addition, a review of scientific papers on the results of clinical studies of the medicinal products for the treatment of the animals for which they are intended may be submitted instead of a report on the results of a clinical study.

As the authors of the initiative pointed out, the law needed to be passed because medicinal products can only be used in the Russian Federation today if they are registered in the respective register. There are two such registers: for medical and veterinary use. Thus, in practice, a veterinarian can use a medicinal product to treat pets only if it is included in the register of medicines for veterinary use. At the same time, even though animals often suffer from the same diseases as humans and their treatment is comparable, the state register of drugs for humans contains over 18,000 products, while the register of drugs for veterinary use contains only about 2,000 products.

The national procedure for registration of medical products at the EEU level was extended until the end of 2025

The member countries of the Eurasian Economic Union have completed the procedure for signing protocols on the extension of the national registration of medical devices until December 31, 2025. Corresponding amendments were made to the Agreement on Unified Principles and Rules for Circulation of Medical Devices within the EAEU dated December 23, 2014.

Previously such possibility was provided until December 31, 2022. It was assumed that from January 1, 2023, registration of medical devices would be carried out only in accordance with the EAEU laws. Extending the deadline set by the protocol will allow member states to improve the system required for the transition to a single registration of medical devices, including clinical centers and testing laboratories. The EAEU Council approved the corresponding plan in December 2022. The implementation of measures under the plan will ensure the unconditional transition to the registration of medical devices by EAEU rules from January 1, 2026.

Note: Please be aware that all information provided in this letter was taken from open sources. Neither ALRUD Law Firm, nor the author of this letter, bear any liability for consequences of any decisions made in reliance upon this information.

Key contacts

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If you have any questions, please, do not hesitate to contact ALRUD partner

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