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Changes in the regulation of medicines circulation in Russia in 2019

This review highlights some significant changes in federal laws and other regulatory legal acts in Russia that regulate the circulation of medicines that become effective in 2019 and obligations of legal entities and individual entrepreneurs – manufacturers and sellers of medicines – in this connection.

1. Releasing into circulation of medicinal products for medical use

Amendments regarding procedures for releasing into public circulation of medicinal products for medical use were introduced to the Federal laws "On Immunoprophylaxis of Infectious Diseases", "On technical regulation" and "On the circulation of medicines" by Federal Law of 28.11.2018 No. 449-FZ (the Law No. 449-FZ).

The current procedure for declaring or certifying medicinal product for medical use is abolished and a new procedure for introducing such medicinal products into circulation (corresponding legal relations are thus excluded from the scope of the legislation on technical regulation) is established.

Before releasing into circulation of each series or each batch of a medicinal product for medical use produced in Russia (with the exception of immunobiological medicinal products) is released into circulation, the manufacturer of such a medicinal product will be required to submit to Federal Service for Surveillance in Healthcare (Roszdravnadzor) a document issued by the respective manufacturer confirming the quality of the medicinal product and of compliance of the means for manufacturing of the medicinal product with the requirements established for its state registration.

With respect to each batch of a medicinal product imported for medical use into Russia, with the exception of immunobiological medicinal products, the importing organization shall submit to Roszdravnadzor before releasing the medicinal product into circulation:

- a certificate of the manufacturer of the medicinal product certifying the compliance of the imported medicinal product with the requirements of the pharmacopoeial monograph, and in the absence of the pharmacopoeial monograph with the requirements of the regulatory documentation, and

- confirmation of the compliance of the imported medicinal product with the requirements established for its state registration, issued by the representative of the importing organization and authorized by a foreign manufacturer of medicinal products.

At the same time, in relation to the first three series or batches of a medicinal product manufactured for the first time in Russia or imported for the first time in Russia, in addition to the abovementioned documents a test report on the compliance of a series or a batch of a medicinal product for medical use with the quality indicators stipulated by regulatory documentation conducted by accredited federal state budgetary institutions (FSBI) should be submitted to Roszdravnadzor.

Each series or each batch of an immunobiological medicinal product produced in Russia or imported into Russia shall be released into civil circulation on the basis of a permit issued by Roszdravnadzor, based on a certificate issued by the FSBI on the conformity of the series or batch of an immunobiological medicinal product to the requirements established during its state registration.

It is not required to submit the above documents and information and to obtain permits to release the immunobiological medicinal product into civil circulation in relation to:

- medicinal products intended for conducting clinical trials, carrying out expert examination of medicinal products for the state registration of the respective medicinal products;

- unregistered medicinal products imported into Russia, intended to provide medical care for the patient's vital medical grounds.

An obligation was established for medicines' manufacturers or organizations importing medicines to Russia to submit annually no later than 1 February to Roszdravnadzor a report upon results of the test of a medicinal product of a particular manufacturer released into circulation during a year (for one series of each trade name, including dosage form and dosage), conducted by accredited testing laboratories (centers). This requirement became effective on 28 November 2018.

In addition, medicines' manufacturers or organizations importing medicines to Russia must notify Roszdravnadzor and the Ministry of Health and Social Development at least one year before the planned suspension or cessation of the production of medicines or their import into Russia.

Medicinal products for medical use released into civil circulation before 1 January 2020, are subject to storage, transportation, release, sale, transfer, application without application of identification means until their expiry date.

The procedure for releasing into civilian circulation of medicinal products for medical use provided for by Law No. 449-FZ becomes effective on 29 November 2019.

2. System for monitoring the medicines circulation

From 1 January 2020 the federal state information system for monitoring the circulation of medicines for medical use from the manufacturer to the end user with the application of identification marks (the "system for monitoring the medicines circulation") will start functioning in Russia.[1]

Legal entities and individual businessmen engaged in the production, storage, import, release, sale, transfer, use, and destruction of medicines will have to ensure that information on the medicines is entered in the system for monitoring the medicines circulation.

The information contained in the system for monitoring the medicines circulation will be placed on the Internet (including in the form of open data).

Manufacturers of medicines will be required to place on primary packaging (if no secondary packaging is provided for the relevant medicines) and secondary (consumer) packaging of medicines for the medical use the identification marks. An exception is provided for the medicines for medical use that are:

- produced for clinical trials, export;

- not subject to state registration;

- intended for use in the conditions of military operations, emergency situations, prevention and treatment of diseases caused by the adverse chemical, biological, radiation factors, and developed on the instructions of the federal executive authorities in the area of national defense and state security.

The manufacturing or sale of medicines for medical use without the identification marks, in violation of the established procedure for such marking, as well as the late entry of data or entry of false information into the system for monitoring the medicines circulation shall involve the liability for legal entities and individual businessmen in accordance with legislation[2].

The Resolution No. 1556 of 14 December 2018 approved the Regulations on the System for Monitoring the Circulation of Medicinal Products for Medical Use ("Regulations on the System for Monitoring the Medicines Circulation"), which establishes, in particular:

- characteristics of the means of identification (a unique sequence of characters presented in machine-readable form or using other means (technology) of automatic identification that is applied to the packaging of medicinal products using printing or labeling methods), the procedure for its application and the requirements for the structure and format of the information that the tool contains identification;

- the procedure for obtaining from the operator of the monitoring system of monitoring codes by (a) manufacturers of medicinal products, carrying out the production stage of packaging (packaging) of medicinal products with application of identification means to the secondary (consumer) packaging of the medicinal product (and, if it is not available, to the primary packaging of the medicinal product), during manufacturing of the medicinal product in Russia, as well as (b) holders of registration certificates of a medicinal product - in the course of manufacturing of a medicinal product outside the territory of Russia, (c) representative offices of foreign organizations in Russia, which are holders of a registration certificate, when producing a medicinal product outside of Russia (issuers of identification tools);

- rules for the creation, commissioning, operation and decommissioning of the monitoring system;

- the procedure for interaction of the monitoring system with other state information systems and information systems of the subjects of the circulation of medicines;

- the procedure for entering information about medicinal products into the monitoring system by medicinal products circulation entities and its composition;

- the procedure for providing information contained in the monitoring system.

Regulations on the System for Monitoring the Medicines Circulation entered into force on 24 December 2018, with the exception of certain provisions.

By the Resolution of the Government of the Russian Federation No. 1557 of 14 December 2018, the procedure for implementing the system for monitoring the medicines circulation is provided for.

The following responsibilities of legal entities and individual entrepreneurs - subjects of the circulation of medicines and the timing of their execution are established:

Responsibilities	Timing
Subjects of circulation of medicines intended for the treatment of persons with hemophilia, cystic fibrosis, pituitary nanism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, persons after transplantation of organs and (or) tissues must:	

be registered in the system for monitoring the medicines circulation (hereinafter referred to as the "monitoring system")	from July 1, 2019 to July 8, 2019 or within 7 calendar days from the day when for the subjects of circulation of medicinal products it is necessary to take up activities related to the circulation of medicinal products but not earlier than July 1, 2019, if you have the right to carry out such activities
ensure readiness for information interaction with the monitoring system and send an application to the monitoring system operator for testing information interaction processes	within 21 calendar days from the date of registration in the monitoring system
to test the processes of information interaction of its own information resource and monitoring system in the manner posted on the official website of the operator of the monitoring system on the Internet for all operations performed with medicinal products in accordance with the Regulations on the System for Monitoring the Medicines Circulation	within 2 calendar months from the day when the own information resource is ready for information interaction with the monitoring system
to enter into the monitoring system information about medicinal products and about all operations performed with medicinal products, in accordance with the Regulations on the system for monitoring the movement of medicinal products for medical use	starting from October 1, 2019
Manufacturers of medicinal products in relation to which they carry out technological operations corresponding to the production stages of packaging (packaging) medicinal products (in the case of production of a medicinal product in Russia), or holders of registration certificates of medicinal products or representative offices of foreign organizations in Russia - holders of registration certificates of medicines (in the event of manufacturing of a medicinal product that outside the territory of Russia), before entering medicinal products into circulation are obliged:	
send an application to the operator of the monitoring system (in electronic form) for receiving an equipment for registering the emission of the means of identification of medicinal products or for providing remote access to such equipment	within 21 calendar days from the date of registration in the monitoring system
ensure the application of the identification means of the medicinal product to the primary packaging thereof (if no secondary packaging is provided) and to the secondary (consumer) packaging of the medicinal product	from October 1, 2019

Subjects for the circulation of medicinal products that do not carry out retail sale of medicinal products and ensure the withdrawal of medicinal products from circulation through the release of free or discounted prescription medicinal products for medicinal products must:	
send, using the monitoring system, an application to the operator of the monitoring system (in electronic form) for receiving registrars of disposal	within 21 calendar days from the date of registration in the monitoring system

The operator of the monitoring system shall provide, among other things, the subjects of medicinal products circulation with equipment for registering the emission of the means of identification of medicinal products, within 30 calendar days from the date of receipt of the applications from these subjects. Subjects of circulation of medicines need to enter into contracts with the operator of the monitoring system, including, inter alia, the conditions for the provision of such equipment and its routine maintenance free of charge.

In accordance with the Order of the Government of the Russian Federation No. 2828-p dated 18 December 2018, the functions of the operator of system for monitoring the medicines circulation starting from 1 January 2019 are performed by OJSC "Operator-CPRT".

3. Test purchases of medicines and medical devices

According to the amendments to the Federal Laws "On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Implementation of State Control (Supervision) and Municipal Control", "On the Circulation of Medicines" and "On the Principles of the Protection of Citizens' Health in the Russian Federation" [3], Roszdravnadzor, when conducting state control over the circulation of medical devices, as well as state control (supervision) in the field of medicinal product circulation, has the right to make test purchases of circulating medicinal products and medical devices.

Roszdravnadzor, thus, will be able to quickly identify falsified, poor quality and counterfeit medical devices and medicines, identify cases of violations by the subjects of circulation of medicines, retail trade of medicinal products, the rules for dispensing medicinal products for medical use, as well as within the framework of state quality control and safety of medical activities to conduct compliance of medical organisations with order and conditions for the provision of paid medical services.

The respective amendments entered into force on 7 January 2019.

4. Lists of medicinal products

The following new lists of medicinal products were approved by the Order of the Government of the Russian Federation of 10.12.2018, No. 2738-r:

- The List of Essential and Essential Medicinal products (VED) for medical use for 2019;

- The List of medicinal products for medical use, including medicinal products for medical use, appointed by decision of medical commissions of medical organizations;

- The List of medicinal products intended to provide persons with hemophilia, cystic fibrosis, pituitary ganosis, Gaucher disease, lymphoid, hematopoietic and related tissues with malignant sclerosis, and persons after organ and / or tissue transplantation;

- The minimum assortment of medicinal products required for medical care.

The List of Vital and Essential Medicinal products for 2019 is supplemented with 38 medicinal products and 2 new dosage forms for medicinal products already included in this list and includes a total of 735 medicinal products (in 2018, this list included 699 medicinal products).

The list of medicinal products to provide certain categories of citizens is supplemented with 27 medicinal products, 3 new dosage forms for medicinal products already included in this list.

The list of expensive medicinal products is supplemented with 1 medicinal product.

In the minimum assortment of medicinal products required for medical care, 1 antiviral medicinal product is additionally included. These lists entered into force on 1 January 2019.

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[1] Pursuant to the changes in the Federal Law 'On Circulation of Medicines' introduced by Federal Law No. 425-FZ, dated 28 December 2017

[2] In particular, violations in marking medicines may involve administrative liability for the manufacturers in accordance with Article 15.12.1 of the Administrative Code.

[3] Introduced by Federal Law No. 511-FZ of December 27, 2018

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Contacts:
Yana Dianova
Director of Corporate and Commercial Law Department
GRATA International (Moscow)
Tel: +7 (495) 660 11 84
E-mail: ydianova@gratanet.com

Салалар

ФАРМАЦЕВТИКА ЖӘНЕ ДЕНСАУЛЫҚ САҚТАУ

Өңірлер

РЕСЕЙ

Маңызды байланыстар

Yana Dianova

Counsel, Corporate and Commercial

Москва, Ресей

+7 495 660 1184

+7 906 734 6817

ydianova@gratanet.com