

CORONAVIRUS RESOURCE CENTER

COVID-19: Changes in the Regulations for the Circulation of Drugs and Medical Devices in Russia

May 11, 2020

The global spread of the COVID-19 pandemic, as well as the unprecedented measures introduced by states in response, has accelerated changes in the regulatory framework relating to the circulation of drugs and medical devices in the Russian market. The relevant changes to the Russian laws provide for the following:

- The legalization of the sale of drugs online, which had been subject to debate since 2017;
- New powers for the Government of the Russian Federation to introduce simplified procedures for state registration and circulation of drugs and medical devices for the prevention of emergency situations (“emergencies”) and for the prevention and treatment of diseases that are dangerous to people (“dangerous diseases”) (“extraordinary circumstances”);
- New powers for the Government of the Russian Federation to limit the circulation of certain types of medical devices in the event of an emergency and/or the threat of a dangerous disease spreading;
- The introduction of special procedures, effective until January 1, 2021, for the state registration and circulation of drugs and medical devices; and
- The automatic renewal of registration certificates for drugs expiring in 2020.

The Debevoise *Coronavirus Resource Center* (go to [link](#)) contains updated guides on a wide variety of situations related to the spread of COVID-19, on Russian law and the laws of a number of foreign jurisdictions, including English law, New York (state) law and French law.

Online Sales of Drugs

A Presidential Decree dated March 17, 2020 allowed for the online sale of over-the-counter (OTC) drugs by pharmacies authorized by the Federal Service for Surveillance in Healthcare (“Roszdravnadzor”)¹. On April 3, 2020, the online sale of drugs became subject to federal law.²

The Decree on Online Sales and the Law on Online Sales established the following procedure for the online sales of drugs in Russia:

- **Allowed:** Online sale of OTC drugs.
- **Not allowed:** Online sale of prescription drugs, as well as narcotic drugs and psychotropic substances, and alcohol-containing drugs with an ethanol content volume exceeding 25%.
- **Sellers:** Only pharmacies that hold licenses for pharmaceutical activity and have been approved by Roszdravnadzor may sell drugs online. Retailers (stores, supermarkets, etc.) may not sell drugs online.
- **Requirements imposed on pharmacies.** The requirements that will have to be complied with by pharmacies that have the right to sell drugs online will be established by the Government of the Russian Federation. The Russian Government has yet to publish these requirements. According to publicly available information³ on the draft resolution being prepared, to sell drugs online a pharmacy must have (a) a license for at least one year; (b) at least 10 pharmaceutical sites in a constituent entity of the Russian Federation; (c) a website or mobile phone application that allows users to select from a variety of payment methods; (d) its own or contracted courier service with cold chain capabilities; and (e) an electronic and/or mobile payment system to pay for goods at the place of service.
- **Monitoring of drug flow.** The pharmacy will be required to enter information on drugs that have been released and received into a drug flow monitoring system. The introduction of the drug flow monitoring suggests that drugs will have to be marked with a barcode that will be scanned at each stage of the drug’s circulation in order to

¹ Presidential Decree No. 187 “On Retail Trade in Drugs for Medical Use” (“Decree on Online Sales”) dated March 17, 2020.

² Federal Law No. 105-FZ “On Amendments to Article 15.1 of the Federal Law “On Information, Information Technologies and Information Protection” and the Federal Law “On Circulation of Drugs” (“Law on Online Sales”) dated April 3, 2020.

³ <https://pharmvestnik.ru/content/news/Pravitelstvo-razrabotalo-poryadok-vydachi-razreshenii-na-distancionnuu-torgovlu-lekarstvami.html>

update information relating to the drug's circulation on the monitoring system. The monitoring system for all drugs is expected to launch on July 1, 2020.

- **Delivery:** The rules relating to the delivery of drugs sold online have yet to be published by the Government of the Russian Federation. According to publicly available information on the draft resolution being prepared,⁴ drugs may be delivered only within the territory of the Russian Federation in which the pharmacy is located and the settlements bordering it.
- **Sales rules:** The rules relating to the sale of drugs online have yet to be established by the Government of the Russian Federation. According to publicly available information on the draft resolution being prepared,⁵ pharmacy employees, while taking orders, will have to inform customers, among other things, about the suggested uses of the relevant drugs and how they would interact with other drugs. Medicines with different storage requirements must be packed separately. Customers ordering thermolabile drugs may demand proof of compliance with the applicable delivery and storage requirements. Customers will also be entitled to withdraw from a purchase without paying for the delivery.
- **Blocking websites for violations:** The online sale of drugs by persons/entities that do not have the necessary license and/or permission of Roszdravnadzor, as well as the online sale of drugs which may not be sold in this way, may lead to including the website on the Unified Register of Domain Names, Website References and Network Addresses That Allow Identifying Websites Containing Information, Circulation of Which Is Forbidden in the Russian Federation ("Register"), and its subsequent blocking. Once Roszdravnadzor determines that a website should be included on the Register, the Federal Service for Supervision in the Sphere of Telecom, Information Technologies and Mass Communications will notify the website host about the inclusion of the website on the Register. The website host will then be required to send a notice to the website owner about the need to remove information relating to the online sale and distribution of drugs in violation of the law. The host may be required to restrict access to the website if the website owner fails to comply with the demand to remove such information.⁶

⁴ <https://pharmvestnik.ru/content/news/Pravitelstvo-predlozilo-ogranichit-zonu-dostavki-lekarstv-onlain-aptkami.html>.

⁵ <https://pharmvestnik.ru/content/news/Pravitelstvo-razrabotalo-poryadok-vydachi-razreshenii-na-distancionnuu-torgovlu-lekarstvami.html>.

⁶ Article 15.1 of Federal Law No. 149 "On Information, Information Technologies and Information Protection" dated July 27, 2006.

Despite the existence of legislative regulation, drugs are still not being sold online because, as noted above, the Government of the Russian Federation has yet to adopt the necessary regulations.

Expansion of the Authority of the Government in the Field of Regulations for Circulation of Drugs and Medical Devices

Since April 1, 2020, the authority of the Russian Government in the event of an emergency or the threat of an emergency has expanded significantly.⁷ In particular, the Government has been given the authority:

- to determine the procedure for the state registration of drugs and medical devices intended for use in an emergency, as well as other matters relating to the circulation of such drugs and medical devices;⁸ and
- to establish restrictions on the wholesale and retail sale of certain medical devices for a period not exceeding 90 calendar days.⁹

In addition, as of April 3, 2020, in the event of an emergency and/or the threat of an outbreak of a dangerous disease, the Government of the Russian Federation will have the power to establish a temporary procedure for the online sale of drugs (including prescription drugs, but with the exception of narcotic and psychotropic drugs as well as alcohol-containing drugs with an ethanol content exceeding 25%), to determine the procedure for issuing permits for such trade, to establish requirements for pharmacies that can carry out such trade, and to establish temporary rules for the delivery of drugs to citizens. These powers will be effective until December 31, 2020.

⁷ We have reviewed these powers in detail in our report dated April 9, 2020, which can be found [here](#).

⁸ Articles 7 and 10 of Federal Law No. 98-FZ “On Amendments to Certain Legislative Acts of the Russian Federation on Emergency Prevention and Management” dated April 1, 2020.

⁹ Government Decree No. 431 dated April 3, 2020 established restrictions on wholesale and retail trade in certain protective equipment (masks, respirators, gloves, etc.) but, from April 22, 2020, these restrictions were suspended.

Accelerated Registration of Drugs

As of April 14, 2020, an accelerated procedure for the state registration of drugs intended for use in emergencies was introduced.¹⁰ This procedure involves the following:

- Registration will be carried out by the Ministry of Health of the Russian Federation (“Ministry of Health”);
- An application for state registration and the required accompanying documents may be submitted in electronic form;
- It is sufficient, to fulfill the requirement to provide clinical documents, to provide a summary report of the results of the effectiveness and safety studies of the drug that are available at the time of application, instead of the full results of clinical trials. However, if summary reports are submitted, the Ministry of Health may impose additional conditions for the circulation of the drug, including restrictions on use, obligations to notify Roszdravnadzor about each use case, mandatory post-registration clinical trials, mandatory batch-by-batch selective quality control and labeling requirements;
- A reduced registration period of 20 working days;¹¹
- An examination of the quality of the relevant drugs and an assessment of the expected benefit-to-possible-risk ratio may not be necessary for drugs already registered in EU Member States, the United States of America, Canada or other states prescribed by the Ministry of Health.¹² For such drugs, their registration may be completed within five working days but the drugs may be subject to batch-by-batch selective quality control and mandatory post-registration clinical trials; and
- The registration certificate for a drug registered under the accelerated procedure will be valid until January 1, 2021. However, the drugs may remain in circulation in the Russian Federation until their expiry date.

¹⁰ Decree of the Government of the Russian Federation No. 441 “On the Specifics of the Circulation of Medical Drugs That Are Intended for Use in a Threat of an Emergency, Emergency Occurrence and Management and for the Organization of the Provision of Medical Assistance to People Affected by an Emergency, Prevention of Emergency Situations, Prevention and Treatment of Diseases That Are Dangerous to Other People, Diseases and Lesions Resulting from the Exposure to Adverse Chemical and Biological Conditions” (“Decree on Accelerated Registration of Drugs”) dated April 3, 2020.

¹¹ In the regular course of business, the period for state registration is 160 working days.

¹² This list has not been established yet.

The accelerated procedure for state registration of drugs will be in effect until January 1, 2021.

Permit for Temporary Circulation

In accordance with the Decree on Accelerated Registration of Drugs, until January 1, 2021, in the event of an emergency, the Ministry of Health may issue permits for the temporary circulation of drugs in the Russian Federation that have not been registered in the Russian Federation but have been permitted for medical use in foreign countries.

A temporary circulation permit may be issued if a drug:

- has no registered analogues in the Russian Federation with the same active substances and pharmaceutical forms, or
- has registered analogues in the Russian Federation, with only one active substance and one pharmaceutical form, with a predicted consumption during the emergency that exceeds the predicted volume of its import or production in the Russian Federation.

The permit for temporary circulation may be issued within two working days and will remain valid until January 1, 2021, but the circulation of imported drugs in the territory of the Russian Federation will be allowed until their expiry date.

Determining the Maximum Selling Price for Vital and Essential Drugs

A special regime has been established for determining the maximum selling price for vital and essential drugs (VED) during emergencies. This regime will be in effect until January 1, 2021.

The Ministry of Industry and Trade of the Russian Federation and Roszdravnadzor conducts quarterly monitoring of the availability of VEDs in circulation. Defects or inadequacies in the circulation of VEDs due to their pricing would be reported to the Ministry of Health. The Ministry of Health would then notify the holder of the registration certificate for the relevant VED of the proposed state registration of the maximum selling price for the VED, which will remain effective for the duration of the emergency situation. The holder of the registration certificate will be able to submit all necessary documents in electronic form through a personal account. The new maximum selling price will be subject to approval by the Federal Antimonopoly Service

of the Russian Federation and will be registered for the duration of the emergency situation.

Special Mechanisms for Circulation of Medical Devices

As of April 6, 2020, special mechanisms for the circulation of certain medical devices intended for use in emergency situations were introduced, which will remain in effect until January 1, 2021. The list of medical devices to which the special mechanisms apply include, in particular, various types of mechanical ventilators, SARS coronavirus tests and protective equipment.

In accordance with the Decree on Circulation of Medical Devices:

- documents for the state registration of medical devices may be provided in electronic form;
- during an emergency situation, conformity assessments, including of technical tests, toxicological studies and clinical trials, for the purposes of state registration, will not be mandatory. During the process of state registration, the relevant expert institution will rely on the studies provided by the applicant. However, the relevant medical devices will have to be re-registered at a later time;
- the state registration process will take up to six working days; and
- the registration certificate for a batch of medical devices will be effective until January 1, 2021.

During an emergency situation, unregistered medical devices included in the list of medical devices to which the special mechanisms apply may be imported into Russia to the extent necessary for testing and state registration, without obtaining permission from Roszdravnadzor. However:

- unregistered disposable medical devices are allowed to be sold in the Russian Federation without permission from Roszdravnadzor if they are registered in their country of manufacture; and
- reusable medical devices that are not registered in the Russian Federation should be disposed of or removed from the Russian Federation after January 1, 2021.

Extension of Licenses and Compliance with License Requirements

Licenses for the production and circulation of ethanol, other alcohols and alcohol-containing products, as well as registration certificates for medical and veterinary drugs, which have expired or will expire between March 15 to December 31, 2020, benefit from a 12-month extension.¹³

On-site inspections of license applicants, licensees and on-site inspections typically necessary as part of the process to obtain, reissue and renew permits may now be conducted via remote controls, photo, audio and video equipment and videoconferencing.

* * *

For more information regarding the legal impacts of the coronavirus, please visit our [Coronavirus Resource Center](#).

Please do not hesitate to contact us with any questions.

MOSCOW



Alyona Kucher
ankucher@debevoise.com



Anna Maximenko
avmaximenko@debevoise.com



Elena Klutchareva
emklutchareva@debevoise.com



Anastasia Magid
ammagid@debevoise.com

¹³ Decree of the Government of the Russian Federation No. 440 “On Extension of Permits and Other Specifics of Permitting Activities in 2020” dated April 3, 2020.