

Rules approved for retail distance selling of pharmaceuticals for medical use

May 2020

As reported in a [previous alert](#) from Dentons' Life Sciences practice, laws and regulations lifting barriers to online sale of some categories of goods were adopted in March-April 2020. At the same time, the liability for violations in this area got tougher.

The Russian Government has now approved the Rules for Issuing Permits for Retail Distance Selling of Pharmaceuticals for Medical Use ("**medicines**"), for making such sale and delivery of medicines to individuals for pharmacy organizations holding a pharmacy license. It did so in its Resolution No. 697 of May 16, 2020, which also approved the relevant changes to the Rules for Selling Certain Types of Goods approved by RF Government Resolution No. 55 of January 19, 1998. The new Government Resolution also vested Roszdravnadzor with the appropriate authority.

We would like to acquaint you with the key changes.

1. What medicines can now be sold by distance selling?

All medicines except:

- Prescription drugs
- Narcotics and psychotropics
- Alcohol-containing drugs with more than 25% ethyl alcohol

2. What does retail distance selling mean?

Receipt, filling, storage and delivery of orders for medicines, and also dispensing of medicines.

3. What are the requirements for pharmacy organizations?

License: The pharmacy must have held a pharmacy license stating that it does work (provides services) for retail sale of medicines for at least one year.

Ten locations: The pharmacy must have at least 10 pharmacy locations in the Russian Federation.

Special premises: The pharmacy must have premises equipped to store orders that have been filled and the premises must comply with the Good Manufacturing Practice Rules for Storage and Shipment of Pharmaceuticals for Medical Use.

Website: The pharmacy must have a website or mobile app.

Courier service: The pharmacy must have its own courier service with equipment for temperature-controlled shipping or a contract with such a courier service.

Electronic payment system: The pharmacy must have an electronic and/or mobile payment system that enables payment for product at the point of service.

4. What is the Roszdravnadzor permit issuance procedure?

The pharmacy organization must submit a permit application to Roszdravnadzor with attached documents/information confirming that it meets the above requirements. Roszdravnadzor will issue a regulation approving the list of documents/information and the application and permit forms separately. The draft regulation is undergoing public discussion until June 4, 2020.

A permit will be issued within five business days and can be applied for online. Information about an issued permit will be entered in a register of pharmacy organizations approved to do distance selling published on the regulator's website.

5. What is the correct way to distance sell and deliver medicines?

Information on the website/in the mobile app

The information must contain:

- The legal entity's name in Russian, its details and hours of operation
- Information about the pharmacy license and retail distance selling permit for medicines
- Information about the medicine ordering service, helpdesk (phone number, email address) and the employee responsible for publishing information about medicines
- Detailed information about medicines that are in stock
- Information about the conditions for retail distance sale, delivery and payment for medicines, of promotions and discounts on the medicines being sold
- Information about the laws and regulations covering possible return of poor-quality medicines
- Information about competent federal executive authorities overseeing the retail distance sale of medicines (including name, telephone number and email address)
- The customer's obligations

Ordering

Medicines can be ordered by contacting the pharmacy directly through the website/mobile app or by calling the pharmacy's ordering service.

The pharmacy employees must:

- Inform the customer of the indications for using the medicine, the retail price of the medicine, the sell by date, purchasing terms, storage precautions and interaction with other medicines
- Make the agreement for retail sale and delivery with the customer, as appropriate
- Discuss with the customer whether it is necessary to provide documents confirming the quality of the

medicines when they are delivered to a place where the pharmacy is not located

The medicines are dispensed according to the rules approved by the Ministry of Healthcare of Russia for dispensing of pharmaceuticals for medical use, including immunobiologicals, by pharmacies and individual entrepreneurs holding a pharmacy license.

Packaging

The order must be packaged in sealed packaging. Orders containing medicines with different storage and/or delivery conditions must be packaged in multiple sealed shipping packages.

The order must have a list of contents stating the order number, date and time picked, and the list must be signed by an authorized pharmacy employee.

Payment

The customer can choose whether to pay for the medicines and delivery services in cash or by cashless payment in advance or upon receipt of the order.

Delivery

The order is delivered to the customer or to any person who is able to confirm payment for the order, at the customer's place of residence, stay or physical location.

Checking the order

After receiving the order, the customer must check that the packaging is intact, open it and check the contents against the list. If temperature-sensitive medicines are being delivered, the customer may ask the employee making the delivery to confirm that the temperature conditions met the required storage standards. The customer must sign for receipt of the order and confirm that there are no complaints to the pharmacy or delivery service.

Right to reject an order

The customer may reject the delivered medicines before paying for them, but will have to pay for delivery. If a delivered order is of poor quality, the customer may return the order without paying for delivery or the delivered medicines themselves and/or request that the order be filled properly.

Confidentiality

The pharmacy shall keep the customer's personal data confidential in accordance with applicable law.

6. What are the penalties for pharmacies failing to comply with the retail distance sale procedure?

Pharmacies that have obtained a permit for retail distance sale are liable according to the new versions of Article 6.33 of the RF Administrative Offenses Code and Article 238.1 of the RF Criminal Code (for more detail on this see our [previous alert](#)).

In addition, a retail distance selling permit issued by Roszdravnadzor may be revoked if:

- The pharmacy organization's pharmacy license has expired or ceased to be effective.
- The pharmacy organization no longer meets the requirements for getting a permit.
- The pharmacy organization has been subjected to administrative liability under articles 6.33 and 14.4.2 of the Administrative Offenses Code two or more times within one year of the date of receipt of the permit, for dealing in falsified, counterfeit, poor quality and unregistered medicines, and for violating the laws on the circulation of medicines.
- The pharmacy organization itself has decided to stop retail distance selling of medicines.

* * *

Resolution No. 697 is a second-tier act with regard to the laws and regulations adopted in March-April 2020 giving the "green light" to retail online sale of medicines. Some provisions of the new rules supplement and partially duplicate the requirements of the consumer protection laws, which will also fully apply to online sales of medicines.

These rules do not deal with the sale of medical devices and dietary supplements. Distance sale of medical devices is not prohibited by law. As for dietary supplements, they must still be sold in compliance with the requirements of Federal Law No. 61-FZ "On the Circulation of Medicines" of April 12, 2010, in terms of the requirements to the operation of pharmacy organizations, and with the requirements of SanPin 2.3.2.1290-03 "Hygienic Requirements for the Organization of Production and Sale of Biologically Active Dietary Supplements."

Notably, the new regulation essentially does not allow for marketplaces and other online selling platforms to do retail distance selling of medicines on their own, forcing them to seek new solutions and operating models in order to comply with lawmakers' requirements.

Dentons provides comprehensive legal support for Russian and international manufacturers, online

platforms and pharmacy chains on the regulation of distance selling of medicines, medical devices and dietary supplements. We also support clients during regulatory inspections and provide recommendations on how to mitigate and eliminate risks that have been identified.

Contacts

Sergey Klimenko

Partner, Head of Russian Life Sciences practice

T: +7 495 644 05 00

E: sergey.klimenko@dentons.com



Vladimir Sokov

Partner

T: +7 495 644 05 00

E: vladimir.sokov@dentons.com

