

Distance selling of medicines legalized and liability for violations related to online sale of medicines tougher

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Newly adopted laws are clearing the way for online sale of medicines in Russia. The changes affect over-the-counter and some prescription medications. There is now also harsher liability for violations in the online sale of medicines.

Dentons' Life Sciences practice would like to acquaint you with the key changes.

1. *Distance selling of medicines permitted and regulated*

Russia's State Duma, the lower chamber of the Federal Assembly of the Russian Federation, recently adopted the Federal Law on Amendments to Article 15 of the Federal Law on Information, Information Technologies and Protection of Information and the Federal Law on the Circulation of Medicines (the "**Medicine Distance Selling Law**"). The State Duma had been considering it since October 2017 and the law has been refined many times following public hearings.

- Among other things, it **changes the definition of pharmaceutical activity to include distance selling of medicines**. Similar additions on possible distance selling have also been included in the definition of pharmacy and veterinary pharmacy activity.
- In addition to selling medicines online, pharmacy organizations and individual entrepreneurs holding a pharmacy license are now entitled to do distance selling of medical devices, disinfectants, personal hygiene items, utensils for medical purposes, items and products intended for the care of patients, newborns and children under the age of three years, eyeglasses and eyeglass care products, mineral water, medical, baby and diet food products, dietary supplements, fragrances and cosmetics, medical and health education publications designed to promote a healthy lifestyle.

We will go into more detail about the implications of these changes in a separate alert.

The adoption of the Medicine Distance Selling Law has changed legislators' approach. The regulator used to be able to block websites containing information about the retail distance selling of medicines, offers to purchase and deliver to an individual all before the trial. Now the regulator's powers are limited to issuing decisions on the basis of which domain names and/or URLs and network addresses are included in the Unified Register of Domain Names, Internet Website Page URLs and Network Addresses Enabling the Identification of Internet Websites Containing Information Prohibited for Dissemination in the Russian Federation (the "**Register**") (which is kept by Roskomnadzor) regarding:

- Information about retail sale of medicines, including distance selling, if such retail sale is restricted or prohibited (e.g., prescription, narcotic and psychotropic drugs, as well as drugs containing more than 25% ethyl alcohol), and/or
- Information about the retail sale of medicines, including distance selling, by entities holding neither a license or a **permit (please see below)** to engage in such activity

The provisions containing the grounds for inclusion in the Register were also entered in Federal Law No. 149-FZ of July 27, 2006, on Information, Information Technologies and Protection of Information.

- The changes also regulate distance retail sale of pharmaceuticals for medical use (except for prescription, narcotic and psychotropic drugs, as well as drugs containing more than 25% ethyl alcohol).

Pharmacy organizations holding a pharmacy license may engage in such sale of medicines.

- Pharmacy organizations will also need to get **a permit from Roszdravnadzor** to engage in retail distance sale.

The Russian Government still needs to determine how such permits will be issued, the requirements for the pharmacy organizations applying for them, how the distance selling will be done, and the rules for shipping and delivery.

All information about medicines that have been paid for (released) and received must be entered in a system that monitors the movement of pharmaceuticals for medical use.

- The Medicine Distance Selling Law also provides that in a state of emergency and/or where there is a risk of spread of a disease that is dangerous for others, the Russian Government is entitled, if necessary, to set up a special temporary policy on distance retail selling. This legislative addition is effective until December 31, 2020.

On March 17, 2020, the President of Russia also signed the Decree on the Retail Sale of Pharmaceuticals for Medical Use. This decree lifts restrictions on the distance selling of medicines that were imposed by Decree of the President of Russia No. 179 of February 22, 1992, on the Types of Products (Work and/or Services) and Production Waste the Free Sale of which is Prohibited.

The government was instructed to increase control over compliance with the laws on the circulation of medicines, including distance retail sale of medicines. In particular, it will focus on preventing the circulation of falsified, counterfeit, poor-quality and unregistered medicines.

The Medicine Distance Selling Law also contains some other changes. In particular, it updates the rule that the executive authorities of Russian Federation constituent entities will establish a list of medical organizations licensed for pharmaceutical activities as well as the list of drugs now including narcotic and psychotropic drugs as drugs that they can sell.

2. Increased liability for online sale violations

To carry out the President's instruction, the State Duma of Russia has adopted laws amending the Administrative Offenses Code and the Criminal Code of Russia to include harsher administrative and criminal liability for selling falsified, counterfeit, poor-quality and unregistered medicines, dietary supplements, or medical devices, and for using **the media or the Internet to commit these offenses.**

This alert details the changes to the Administrative Offenses Code and Criminal Code of Russia related to the legalization of online sale of medicines. Our next alert will address the importance of these amendments for other product categories and their impact on the industry as a whole.

In particular, Article 6.33 of the Administrative Offenses Code now has a third part which sets the administrative

liability for the above offense as an administrative fine of:

- RUB 70,000 to RUB 200,000 for individuals
- RUB 150,000 to RUB 600,000 for officers
- RUB 150,000 to 600,000 for individual entrepreneurs, or administrative suspension of their activity for up to 90 days
- RUB 2,000,000 to RUB 6,000,000 for legal entities, or administrative suspension of their activity for up to 90 days.

The actions will not be deemed an administrative offense if:

- The sale and/or import of unregistered medicines is allowed by the laws on the circulation of medicines and the healthcare laws, and/or
- The medicines are not manufactured in the Russian Federation, and/or
- The medicines are recommended for use by the World Health Organization

It will be considered a crime if more than RUB 100,000 worth of products is sold (there will be a new version of Article 238.1 of the Criminal Code of Russia). The criminal liability for this is:

- Compulsory labor for four to five years, potential disqualification from holding certain positions or engaging in certain activity for two to three years, or
- Imprisonment for four to six years, a potential fine of RUB 750,000 to RUB 2,500,000 or the salary or other income of the convicted person for one to two years, and potential disqualification from holding certain positions or engaging in certain activity for up to four years.

Exceptions apply to the sale and/or import to the Russian Federation for sale of medicines that are not registered in the Russian Federation, if:

- They are not manufactured in the Russian Federation, and/or
- The sale and/or import of such products is allowed by the laws on the circulation of medicines and the healthcare laws, respectively, and/or
- They are recommended for use by the World Health Organization

The newly adopted laws are intended to streamline the process of selling and distributing medicines over the Internet. This is a necessary tool to make medicines available for people, including in a state of emergency. The changes create the legal basis for pharmaceutical companies, pharmacies, aggregators and marketplaces to do online retail sales.

Adoption of the Medicine Distance Selling Law is a serious step toward changing the traditional idea

of how medicines are sold in Russia. It will also help to harmonize approaches to healthcare regulation in Russia with international practices.

Nevertheless, it isn't quite clear yet how these changes will be introduced and implemented in practice. Nor is it clear how introduction and implementation will be monitored considering that, so far, statutory regulation does not do enough to enable this.

Dentons provides comprehensive legal support for Russian and international manufacturers and online platforms 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.

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