



AN EXPERIMENT HAS STARTED IN ONLINE TRADE IN RX-MEDICINES

FAO pharmaceutical companies, pharmacies and healthcare institutions, as well as governmental authorities responsible for the supply of medicines to patients

Pepeliaev Group advises that an experiment started on 1 March 2023 regarding distance trade in prescription medicines.

What? Where? When?

	<p>1 March 2023 until 1 March 2026 An experiment is being conducted in distance retail trade in prescription medicines for medical use.¹</p>
<p>Participants in the experiment are healthcare institutions and pharmacies from the three regions below:</p> <p>Belgorod Region Moscow Region Moscow</p>	
	<p>The legal regulation and administrative management of the experiment has been vested in the Russian Ministry of Healthcare and in the competent executive authorities of Moscow, and of Belgorod and Moscow Regions.</p>
	<p>The list of medicines and pharmacotherapeutic groups of medicines that have been permitted to be sold under the experiment includes 904 International Non-Proprietary Names of all kinds of therapeutic groups, including antibiotics and antiviral agents, anti-cancer drugs, and immunosuppressants. The list has</p>

¹ Federal Law No. 405-FZ "On amending the Federal Law "On the circulation of medicines" dated 20 October 2022 (article 55.1 has been added).

been compiled based on the criteria established by the Government and has been approved by the Ministry of Healthcare.²

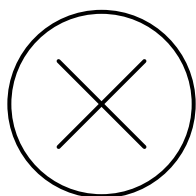
Exceptions

The following groups of medicines have not been included in the list:

- narcotics and their precursors;
- psychotropic substances and their precursors;
- medicines containing potent substances;
- radiopharmaceutical medicines;
- immunobiological medicines;
- medicines which, according to their instructions for use, should be stored at a temperature below 15 degrees Celsius;
- medicines containing alcohol with more than 25% per cent ethyl alcohol by volume;
- medicines that are produced by pharmacies.³

Added to these are the following medicines for which special criteria have been stipulated to be included in the experiment:

- those that are not on the list of medicines of which a record must be kept in a specific manner;
- those that are not anabolic steroids;
- those that are not antipsychotics, anxiolytics, antidepressants, sedatives and hypnotics;
- those that are not used to terminate pregnancy.⁴



Requirements for participants in the experiment

The general requirements for participants in the experiment have been established by the Regulations on the experiment to be conducted in distance trade in prescription medicines for medical use.⁵

Pharmacies will specifically play a key role in the experiment. Pharmacies that participate in the experiment should meet certain criteria to perform distance trade in Rx-medicines:

- be licensed for at least one year to carry out pharmaceutical activity, where such licence should indicate the type of work performed (services supplied) in retail trade in medicines;
- be authorised by the Russian Federal Service on Surveillance in Healthcare (in Russian,

² The Russian Ministry of Healthcare's Order No. 36n dated 1 February 2023 "On approving the list of medicines and pharmacotherapeutic groups of medicines that have been permitted to be sold under the experiment in distance trade in prescription medicines for medical use".

³ Part 2 of article 55.1 of Federal Law No. 61-FZ "On the circulation of medicines" dated 12 April 2010.

⁴ The Russian Government's Resolution No. 2465 "On approving the criteria for medicines and pharmacotherapeutic groups of medicines to be included in the list of medicines and pharmacotherapeutic groups of medicines that have been permitted to be sold under the experiment in distance trade in prescription medicines for medical use" dated 28 December 2022.

⁵ The Russian Government's Resolution No. 292 "On approving the Regulations on the procedure for conducting the experiment in distance trade in prescription medicines for medical use" dated 22 February 2023.

abbreviated to “Roszdravnadzor”) to carry out distance retail trade in medicines, for which purpose a pharmacy must confirm that:

- it has at least one equipped facility to store orders that have been made;
- it has its own website with/without a mobile application or an agreement with the aggregator;
- it has its own courier service and special equipment or an agreement with a courier service that delivers medicines in a prompt and safe manner (for example, by using special boxes which ensure that a specific temperature is maintained);
- it has an electronic system of payments or a mobile payment terminal;
- a licensee should enter information into the unified state healthcare information system regarding the activities of the pharmacy and report information regarding its personnel to the federal register of medical and pharmaceutical employees and the services it supplies as well as Roszdravnadzor’s permission to conduct distance trade in Rx-medicines.

Moreover, regional executive authorities of the constituent entity of the Russian Federation will approve the procedure for selecting healthcare institutions and pharmacies to participate in the experiment.

For instance, the City of Moscow Healthcare Department already approved on 13 March 2023 its Regulation on information exchange when prescriptions are drawn up and used, including in the form of electronic documents, which incorporates technical requirements for information exchange between a pharmacy and the city of Moscow's automated information system titled “The unified medical information and analytical system of the city of Moscow”.⁶

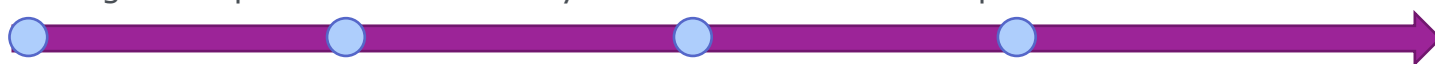
Regional executive authorities will select and approve the final list of healthcare institutions and pharmacies that will participate in the experiment. The above list will be dynamic, meaning that participants in the experiment will be able to withdraw from the pilot project voluntarily or that new participants may enter. Moreover, regional executive authorities will also be authorised to establish specific aspects of how the experiment will be conducted in their constituent entity of the Russian Federation.

π^g | Consequently, regions have been offered an opportunity to independently regulate the rules of the experiment. It has been left for regions to determine the technical aspects of how the experiment should be implemented so that they may promptly change them if the need arises.

⁶ <https://mosgorzdrav.ru/ru-RU/document/default/view/2111.html>

The procedure for joining the experiment

Joining the experiment is voluntary and involves several steps.



1. Filing an application to join the experiment via a personal account at the Unified Portal for State and Municipal Services (Functions)

2. Compiling regional lists of participants in the experiment

3. Obtaining permission from Roszdravnadzor to conduct online trade in Rx-medicines

4. Starting online trade in Rx-medicines

Roszdravnadzor refuses to grant permission to a pharmacy to conduct online trade in Rx-medicines if the pharmacy:

- provided incomplete or inaccurate information in the application;
- is not on the list of the regional executive authority;
- does not meet the established criteria.

The procedure for distance trade

Figure 1 shows how Rx-medicines will be sold distantly.

To buy an Rx-medicine online a purchaser will be required to produce an electronic prescription. The prescription can be drawn up in the form of an electronic document in the individual's personal account at the federal state-owned system "Unified Portal for State and Municipal Services (Functions)" or at regional portals of state and municipal services.

When Rx-medicines are sold distantly, pharmacies and aggregators (if sold through marketplaces) are required to identify the individual to whom the prescription for the medicine was issued against the identity of the individual to whom it was delivered. Hence, the courier must request the recipient of the medicine to produce his/her ID to perform such identification.

If the identity of the recipient of Rx-medicines does not correspond to the identity of the person indicated in the prescription or if the recipient refuses to produce his/her ID, the medicine cannot be handed over to the recipient and must be returned to the pharmacy.

If the recipient is the person indicated in the prescription, then to confirm the fact that the medicine has been delivered, the recipient should sign a special document in an approved format evidencing that he/she received the medicine, in addition to receiving a standard cashier's receipt.⁷ The courier must return the special document to be stored at the pharmacy that dispensed the medicine.

⁷ The Russian Ministry of Healthcare's Order No. 768n "On approving the form of the document evidencing receipt of a medicine for medical use that is dispensed against a prescription for the medicine by the person indicated in the prescription under the experiment in distance retail trade in prescription medicines for medical use" dated 28 November 2022.

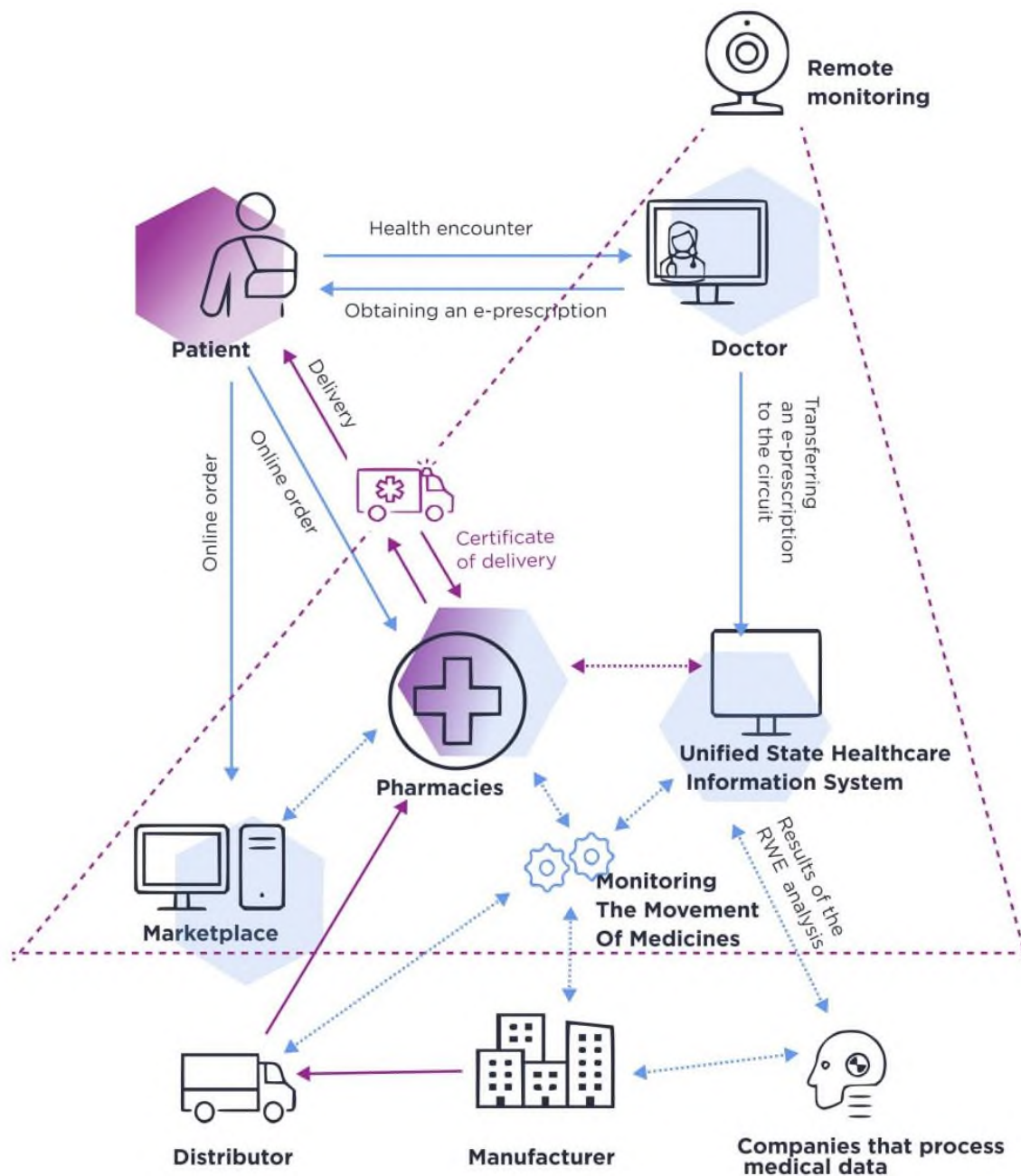


Fig. 1 The procedure for the online sale of prescription medicines

Risks and recommendations for pharmacies

Participants in the experiment should bear in mind that in terms of the procedure for dispensing medicines the experiment does not cancel other requirements that pharmacies are obliged to meet. The fact that a pharmacy is participating in the experiment does not release it from liability for breaching the rules for dispensing medicines or other licence requirements. In other words, the regulatory body does not provide for any exemptions to be granted to participants if things go wrong in the process.

Moreover, pharmacies that participate in the experiment will be given increased attention. Pharmacies will have their licences to sell prescription medicines revoked for a number of violations. Such violations include: a pharmacy being held liable for selling low quality, adulterated or counterfeit medicines (article 6.33 of the Russian Code of Administrative Offences), selling medicines without their label codes being scanned (article 6.34 of the

Code of Administrative Offences), or violating the procedure for retail trade in medicines (article 14.4.2 of the Code of Administrative Offences).

Although under current regulation pharmacies individually assume liability for almost any violations during the online sale of prescription medicines, this does not preclude the possibility of liability being redistributed between the parties under agreements that have been concluded. For example, it is possible to make provision in the agreement with the delivery company for an obligation to compensate the pharmacy for the losses caused by the delivery company through its non-performance or improper performance of its obligations to deliver medicines.

Consequently, compensatory mechanisms can be stipulated by the agreement in case civil law or administrative liability is imposed on the pharmacy for the delivery company or another counterparty violating Russian legislation.

Unresolved issues

If the experiment is a success, the mechanism of distance trade in Rx-medicines that is used under it will be extended which will trigger growth in the market of online trade in prescription medicines. The above rules being applied under the experiment will allow the identification in practice of bottlenecks in the regulation, its challenges and conflicts.

However, it is possible to identify even now a number of unresolved issues that have not been properly regulated by the legislation.

- For example, no course of action has been determined for pharmacies if their licence for distance trade has been revoked: from which moment and within what period the pharmacy/aggregator should remove from their websites the option for ordering Rx-medicines via them. What should happen to orders that have been made but have not been delivered? What should be done with medicines that have been returned to a pharmacy whose online trade licence has been revoked? In fact, once the licence for online trade in prescription drugs has been revoked, any transactions involving delivery of such medicines will constitute a breach of the law.
- Issues remain unresolved concerning the balance between the 'experimental' regulation and the provisions of article 67 of the Federal Law "On the circulation of medicines" (information regarding prescription drugs can be included only in specialist publications designed for healthcare and pharmacy professionals) that have been in effect for a considerable time and of article 24 of the Law "On advertising" (Rx medicines may not be advertised other than in places where medical or pharmaceutical exhibitions, workshops, conferences or other are held).
- Neither article 55.1 of the Federal Law "On the circulation of medicines" nor the Regulations on the experiment eliminate the potential conflict; for instance, are the following methods of online promotion of goods permissible and legal or not: including medicines in a "Recommended" section, or informing users about promotions (including price discounts), or making package offers (buy one, get one free and others).

Meanwhile, the absence of clarity with regard to such issues creates a genuine risk for both pharmacies and aggregators since, despite the 'experimental' nature of the sale of prescription medicines, liability for sellers/advertising agents will arise on general grounds.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide legal assistance to those involved in the pharmaceutical market, including pharmaceutical producers, distributors, pharmacy chains, marketplaces (aggregators) and healthcare institutions with regard to any issues that may arise within the above experiment.

We are ready to provide services that involve reviewing agreements that are being/have been concluded, representing your interests in the event of a dispute with regulatory authorities/counterparties, assessing events promoting the sale of Rx-medicines, and providing legal support in terms of bringing your current business practices in line with legislation.

Contact details



Konstantin Sharlovskiy

Head of the Life Sciences Practice

Tel.: +7 (495) 767 00 07

k.sharlovskiy@pgplaw.ru