

Russia approves rules for online sale of OTC drugs

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The Russian government has approved the [rules*](#) for selling over-the-counter (OTC) drugs online.

The new rules set the conditions for:

- obtaining a permit to sell drugs remotely;
- the requirements for information to be provided to consumers;
- the rules for the delivery of drugs; and
- the conditions for their return.

The rules also clarify the possible negative consequences of online sales in breach of the requirements.

Online sales of OTC drugs were formally legalised in Russia in early April 2020 (see our previous [eAlert](#)). However, that law and the presidential executive order did not establish the procedure for obtaining a permit for this type of sales. The recent government decree addresses this gap by establishing the requirements for pharmacy chains seeking to obtain such a permit.

Conditions for obtaining an online sales permit

In accordance with the new rules, a pharmacy must have a licence for the retail sale of drugs for at least one year and must also have:

- at least ten locations where it sells drugs;
- storage facilities that meet the requirements of good storage and transportation practices for drugs;
- a website and optionally a mobile application;
- a courier service (the pharmacy's own or a contracted service), which has the necessary equipment for the transport of drugs requiring compliance with a special temperature regime (i.e. for thermolabile drugs); and
- an electronic payment system and/or mobile payment terminals.

To obtain a permit, the pharmacy must submit an application and supporting documents to the Federal Service for Surveillance in Healthcare ("Roszdravnadzor"). Decisions are to be issued within five business days. The register for permits issued will be accessible on Roszdravnadzor's website.

Roszdravnadzor will establish the documents confirming compliance with the above requirements, and a more detailed procedure for submitting and considering applications.

Website requirements

The rules set forth the information which must be posted on the e-pharmacy's website. In particular, it is necessary to provide the following: information about the organisation selling online, graphic copies of its licence and permit, information on medicines (including instructions for use), information necessary to protect consumer rights (e.g. online sales rules and a list of the authorities supervising the online sale of drugs) and details on the obligations of buyers.

Delivery terms

Drugs can be delivered either by a pharmacy employee or an employee of the courier service hired by the e-pharmacy. The rules, however, do not establish any requirements for couriers. Hence, a person who does not have a pharmaceutical education can conduct a delivery, but all essential information about the drug (e.g. its interaction with other drugs) must be communicated to the buyer upon receipt of the order.

Drugs must be delivered in accordance with the applicable conditions of their storage and transportation. When thermolabile drugs are delivered, consumers will have the right to request confirmation of compliance with the relevant requirements. In addition, transported drugs must be packaged in such a way that it is possible to control whether they have been opened.

Returning drugs

Although, as a general rule, the return of drugs of good quality is not allowed, good-quality drugs purchased remotely can be returned before payment of the order, subject to payment for the cost of delivery.

Consequences of breaches by online pharmacies

Permit termination

An online sales permit can be terminated if:

- the pharmacy's licence is terminated;
- the pharmacy decides to stop selling online;
- the pharmacy does not meet the requirements to obtain a permit; or
- the pharmacy has been held liable two times or more for violation of the ban on the sale of unregistered, substandard and falsified drugs, or for violation of the procedure for the wholesale and retail sale of drugs.

Site blocking

Roszdraznadvor can decide to block a website when drugs are sold online without a licence and/or permit, or when drugs that are prohibited to be sold remotely are sold online (e.g. prescription drugs).

Conclusion

The new rules have established fairly detailed and stringent requirements for the implementation of online sales of drugs. Nevertheless, it remains formally impossible to sell drugs online until Roszdraznadvor adopts the necessary legal acts and all information systems have been tested. Online drug sales are scheduled to start at the beginning of June 2020 at the earliest.

A pharmacy can now assess whether it meets the requirements and can begin preparing for the launch of an online pharmacy. This entails developing an agreement for working with consumers (i.e. drafting sales rules), adjusting, if necessary, privacy policies posted on websites and concluding an agreement with an organisation to provide courier services.

If you have any questions on this eAlert, do not hesitate to contact CMS Russia experts [Vsevolod Tyupa](#), [Alexey Shadrin](#) or your regular contact at CMS Russia.

* *In Russian*

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