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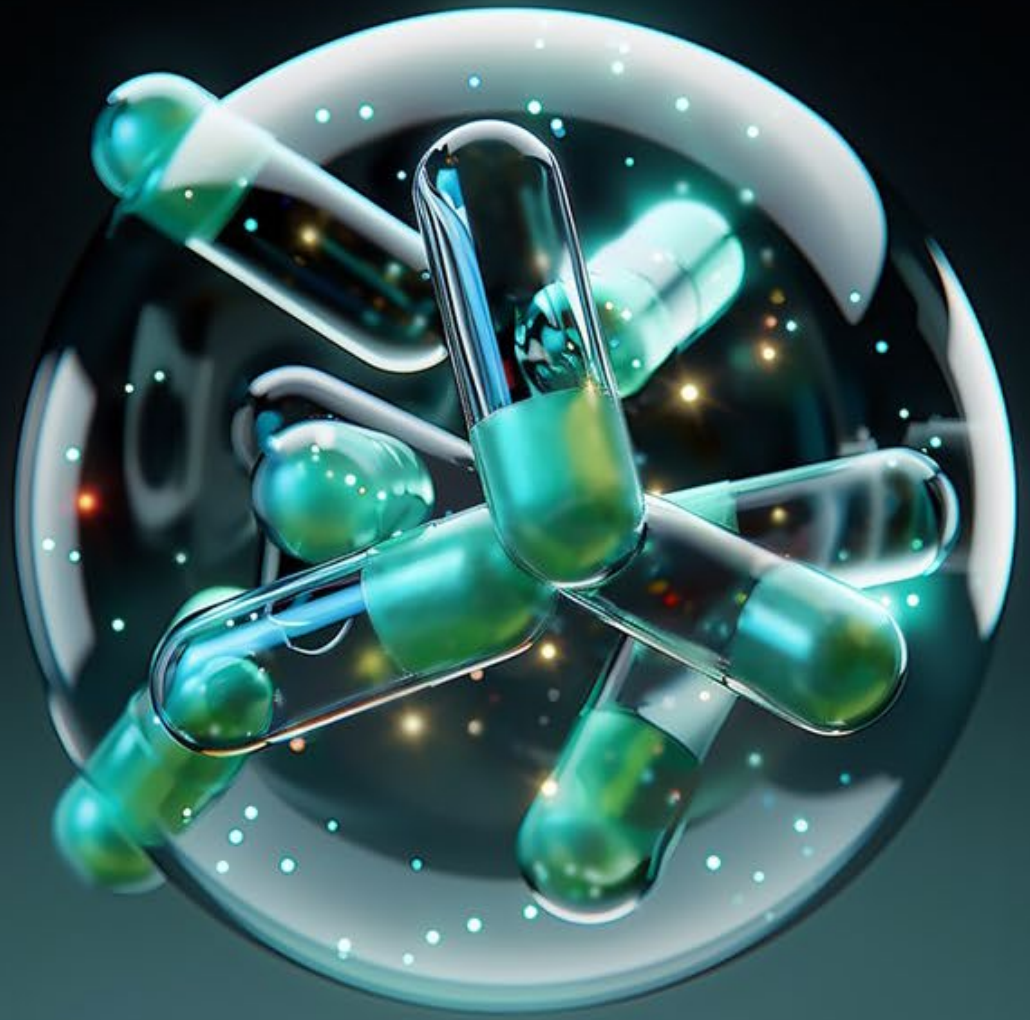

Russian Pharmaceutical Market: Key Legislation

BST Consulting

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Dear colleagues,

The following guidelines represent an attempt to encompass the main existing features in Russian pharmaceutical industry.

Upon including different tax and legal aspects pertaining to the pharmaceutical products enlisted in these guidelines, we have referred to the most problematic and risk-related areas of Russian pharmaceutical industry taking into consideration Russian court and administrative practice as well as our experience of performing projects which were focused on the relative aspects.

Apart from key features of Russian pharmaceutical industry, these guidelines also represent our tax and legal services which could be applicable to particular aspects.

We hope that the following guidelines will be useful in the process of your work and will provide you with a brief outlook of the main areas of Russian pharmaceutical market that are worth taking into account upon performing regular business activities.

In case you have any questions, please feel free to contact us any time convenient for you.

Best regards,

Anastasia Dnishchenko

Contents

General Requirements towards Pharmaceutical Activity in Russia and the EAEU

The Russian legal requirements towards carrying out of pharmaceutical activity are envisaged by both Russian local pharmaceutical legislation as well as by the EAEU laws.
For the purpose of ensuring that the company is entitled to be engaging in entrepreneurial activity of selling medicines, medical devices and nutritional supplements in the territory of the Russian Federation and other EAEU member states, it is necessary to ensure that the company complies with the laws at both local and multinational levels.
In the next slides we summed up general requirements towards carrying out pharmaceutical activity in the Russian Federation and other EAEU states.
At the same time, local pharmaceutical legislation of other EAEU states may differ from Russian rules, which is why it is necessary to make sure compliance with such rules is met on a case by case basis.
We have completed an overview of groups of general requirements applicable to carrying out pharmaceutical activity in the next slides together with the list of BST's services, which may be useful under each step of planning the entering and maintenance in the Russian and EAEU pharmaceutical market.

Obtainment of Pharmaceutical License

Obtainment of Pharmaceutical License

In the Russian Federation, carrying out pharmaceutical activity is subject to obligatory state licensing[(1)].
In case a company intends to be engaged in one of the following types of activity[(2)] constituting pharmaceutical activity (with respect to medicines for human use), it is obliged to obtain a pharmaceutical license from the Russian Federal Service for Surveillance in Healthcare (the "**Roszdravnadzor**"):

- Wholesale trade of medicines
- Storage of medicines
- Transportation of medicines
- Retail trade of medicines
- Dispensing of medicines
- Manufacturing of medicines

Requirements towards obtainment of pharmaceutical license have recently changed with the new ones being effective starting from 1 September 2022 and including, among others, the following:

- Compliance with the EAEU Good Distribution Practice ("GDP")[(3)]
- Compliance with the Good Storage and Transportation Practice ("GS&TP")[(4)]
- Existence in accordance with GDP and GS&TP of a person responsible for introduction and maintenance of the quality system of storage and transportation of medicines and updating standard operational procedures and other requirements.

How can BST help?

Our professionals provide a full range of services related to the process of obtainment of the pharmaceutical license, including:

1. Identification of pharmaceutical activities the client is interested in carrying out in the Russian Federation,
2. Assessment of whether the client meets Russian and EAEU requirements for obtainment of the pharmaceutical license,
3. Preparation of the required application package to be submitted to the Russian state authorities,
4. Submission and interaction with the Russian state authorities throughout the whole process of obtainment of the pharmaceutical license

(1) Federal Law No. 99-FZ dated 4 May 2011 "On Licensing of Particular Types of Activity" (art. 12, p. 1, pp. 47)
(2) Resolution of the Government of the Russian Federation No. 547 dated 31 March 2022 "On Approval of Provision on Licensing of Pharmaceutical Activity" (Appendix)
(3) Decision of the Eurasian Economic Commission's Council No. 80 dated 3 November 2016 "On Approval of GDP within the EAEU"
*(4) Order of the Ministry of Health of the Russian Federation (the "**Minzdrav**") No. 646н dated 31 August 2016 "On Approval of Good Storage and Transportation Practice for Medicines for Human Use"*

Obtainment of Market Authorizations

Obtainment of Market Authorizations (1/2)

For the purpose of entering into civil circulation in Russia and the EAEU member states, medicines are subject to state registration (except for medicines imported to Russia under Compassionate Use Programs)[(5)].

The holder of the market authorizations may be either a local or foreign legal entity.

Starting from 1 January 2022 upon registration of medicines submission of documents sustaining compliance of industrial sites with the requirements of good manufacturing practice ("GMP") shall be made in accordance with the EAEU GMP. At the same time, until the end of a medicine's period of validity applicants are entitled to submit national GMP certificates. Thus, taking into account that national GMP certificates are effective within 3 years, applicants are entitled to submit local documents issued by the EAEU member state prior to 31 December 2021, until 31 December 2024[(6)].

Medical devices currently may also be registered under local rules until 31 December 2022. After this date their registration will be carried out solely in accordance with the EAEU procedures[(7)].

Moreover, for the purpose of decreasing administrative pressure on pharmaceutical manufacturers amid sanctions validity of statements of conformity with GMP (both local and EAEU ones), expiring in 2022, are prolonged for 12 months[(8)].

Finally, amid external economic impact, in case of shortage of medicines or the risk such shortage may occur in the EAEU markets authorities of the EAEU member states are entitled to prolong the validity of market authorizations and GMP certificates whose period of validity expires until the end of 2024[(9)]. Also simultaneous inspections of industrial sites for the purpose of their conformity with GMP requirements as well as conduction of such GMP requirements in post-registration regime is allowed upon submission of the application for registration of medicines until 2023.

How can BST help?

Our professionals provide a wide range of services related to assistance with registration and reregistration of medicines, including collection of and submission of the required package of documents as well as cooperation with the Russian state authorities during the whole process of medicines registration.

(5) Resolution of the Government of the Russian Federation No. 230 dated 5 March 2020 "On Import to the Russian Federation of Unregistered Medicines".
(6) Decision of the Eurasian Economic Commission's Council No. 34 dated 23 April 2021.
(7) Agreement on Unified Principles and Rules of Circulation of Medical Devices within the EAEU dated 23 December 2014
(8) Order of the Ministry and Trade of the Russian Federation No. 1987 dated 18 July 2022.
(9) Decision of the Eurasian Economic Commission's Council dated 10 June 2022 No. 96

Obtainment of Market Authorizations (2/2)

Upon carrying out pharmaceutical activity in the Russian Federation, it is advisable for the medicines to be labelled as the Made in the EAEU medicines.

State preferences for medicines produced in the EAEU:

- pricing benefits at government tenders for medicines (25% for medicines produced out of local APIs, 15% - for other locally produced medicines)
- "three's a crowd rule"
- "two's a crowd rule" is now under consideration with respect to "strategically important" drugs (however, it is already applied to some types of medical devices[10])

"Three's a crowd" rule explained: upon state procurement of VED-listed medicines, the customer (i.e. the state) must decline all tender applications with foreign (origin is outside of the EAEU) in case at least two tender applications with medicines originating from the countries of the EAEU have been submitted.

"Made in the EAEU" status under "three's a crowd rule"/ pricing benefits may be confirmed with

- ST-1 certificate - in Russia issued by the Chamber of Commerce and Industry on the basis of the Treaty on the Rules of Determination of the Country of Origin in the CIS of 20 November 2009 (general rule for medicines - change in any of first 4 digits of the tariff code, packaging in the EAEU is not sufficient for local product status), or
- A confirmation issued by the Ministry of Industry and Trade of the Russian Federation in accordance with the rules approved by the Resolution of the Government of the Russian Federation No. 719 dated 17 July 2015 (an examination report of the Chamber of Commerce and Industry of the Russian Federation or ST-1 is the basis for receiving this confirmation, for Special Investment Contract this confirmation should be issued by default)

How can BST help?

Our professionals provide services on obtainment of documents confirming the "Made in the EAEU" status, including collection of documents for submission to the Russian state authorities and cooperation with them during the whole process of obtainment of required documents.

Compliance with the Track & Trace System Rules

Compliance with the Track & Trace System Rules

Starting from 1 July 2020 all medicines which are manufactured, stored, imported in Russia, sold by legal entities and sole proprietors should be labelled and monitored in the Track & Trace system. All pharmaceuticals should be labelled with special Data Matrix code before being released into free circulation (i.e., placed under the customs procedure of release for free circulation).

Therefore, companies are obliged to register with the Track & Trace system and complete the installing of all the necessary equipment and report every transaction/transfer with the pharmaceuticals. In case companies sell unlabeled medicines or do not submit information in the Track & Trace system, they can become subject to administrative liability.

Given the several delays of entering into force of the provisions on mandatory labelling and overall difficulties companies face with upon implementation of new business processes, the new rules provide that the sale of unlabeled medicines which were produced prior to 1 July 2020 is permitted until their expiration date.

At the moment, some types of medical devices (including hearing devices, tomographs, etc.) shall also be labelled as part of an experiment lasting from 15 February 2022 to 28 February 2023[(11)].

Moreover, currently nutritional supplements are also subject to mandatory labelling as part of an experiment lasting from 1 May 2021 to 31 August 2022[(12)].

(11) Resolution of the Government of the Russian Federation No. 137 dated 9 February 2022 "On Conduction in the Territory of the Russian Federation of the Experiment on Labelling of Particular Types of Medical Devices".
(12) Resolution of the Government of the Russian Federation No. 673 dated 29 April 2021 "On Conduction in the Territory of the Russian Federation of the Experiment on Labelling of Nutritional Supplements".

How can BST help?

We provide tax and legal consulting services on the implementation of the Track & Trace system, including:

- analysis of current business processes, preparation of schemes and descriptions of target business processes;
- analysis of operational, financial, tax and customs risks related to the implementation of the Track & Trace system as well as preparation of recommendations on their mitigation;
- development and implementation of control procedures;
- update or preparation of internal policies/procedures related to the implementation and functioning of the Track & Trace system;
- conduction of trainings/seminars on compliance with legal requirements on the implementation of the Track & Trace system for the company's employees.

Compliance with Pricing Regulation

Compliance with Pricing Regulation

In Russia, all medicines included in the List of Vital and Essential Drugs ("**VED**")[13] are subject to special pricing regulation[14]. These rules set certain requirements towards maximum sale prices ("**MSP**") of such medicines as well as the maximum amount of their wholesale and retail mark-ups.

MSPs of VED-listed medicines

MSPs of VED-listed medicines (in RUB) are subject to registration in the Minzdrav. The properly registered MSPs of VED-listed medicines can be reregistered for the purpose of their increase no more than once in a calendar year provided that specific grounds for the reregistration occur (e.g., reregistration is possible in case of change of prices for raw materials used in production of VED-listed medicines, change of overhead costs, etc.). Reregistration may also take place on obligatory basis in certain cases (e.g., in case of the decrease of price in foreign currency of the medicine in the manufacturer's state, etc.)[15].

Currently special provisions are applied towards registration and reregistration of MSPs of VED-listed medicines, which are applied in case of VED-listed medicines' shortage or risk of occurrence of their shortage envisaging, among other, the speed-up of the MSPs reregistration procedure, amendments to the rules of calculation of MSPs, etc.[16]

MSPs and maximum amounts of wholesale mark-ups are also set with respect to medical devices included in the "List of In Vitro Medical Devices"[17].

VAT treatment of medicines and medical devices.

Sale of goods, services and works in the territory of Russia is subject to VAT at a general rate of 20%. However, with respect to medicines, their sale is subject to a reduced VAT rate of 10% provided that their RCPEA (Russian Classification of Products by Economic Activities) code is included in respective list[18]. VAT rates with respect to sale of medical devices also differ: they are either 20%, 10% or non-VATable depending on the RCPEA code of a particular medical device[19]. At the same time, Russian tax authorities tend to challenge application of the reduced VAT rate, which is why a tax risk may crystalize.

How can BST help?

Our professionals provide a wide range of services related to assistance with registration and reregistration of MSPs, consulting on pricing matters of sale of medicines as well as analysis of VAT tax risks related to sale of medicines.

(13) Decree of the Government of the Russian Federation No. 2406-p dated 12 October 2019 "On Approval of List of VED Medicines as well as List of Medicines for Human Use and Minimum Assortment of Medicines Necessary for Medical Aid" (please note that VED list is subject to amendments on a yearly basis).

(14) Resolution of the Government of the Russian Federation No. 865 dated 29 October 2010 "On State Regulation of VED-listed Medicines".

(15) Federal Law No. 61-FZ dated 12 April 2010 "On Circulation of Medicines) (art. 61).

(16) Resolution of the Government of the Russian Federation No. 1771 dated 31 October 2020 "On Approval of Peculiarities of State Regulation of MSPs on VED-listed medicines and Making Amendments in Separate Acts of the Government of the Russian Federation".

(17) Ruling of the Government of the Russian Federation No. 1517 dated 30 December 2015 "On State Regulation of In Vitro Medical Devices".

(18) Resolution of the Government of the Russian Federation No. 688 dated 15 September 2008 "On Approval of List of Medical Products' Codes Subject to 10% VAT".

(19) Resolution of the Government of the Russian Federation No. 1042 dated 30 September 2015 "On Approval of List of Non-VATable Medical Devices".

Compliance with Promotion Requirements

Stimulation Payments to Pharmacies (1/2)

Main types of stimulation payments

Bonuses | **Types of stimulation payments to pharmacies** | **Payments for rendered services**

Generally, a company's expenses on **bonuses** payable to pharmacies may be deducted for the purpose of profits tax. However, certain tax risks may occur upon making such payment

For example, Russian tax authorities may:

- claim additional profits tax – in respect of the company paying bonuses – due to absence of economic justification and/or document support of its expenses on bonuses payable to pharmacies;
- claim additional VAT – in respect of the company receiving bonuses (i.e., a pharmacy) – due to requalification of bonuses into payments for rendered services.

A company's expenses on **payments for rendered services** to pharmacies are also generally profits tax deductible. Nonetheless, the Russian tax authorities tend to challenge such expenses too in the followings ways:

- claim additional profits tax – in respect of the company paying for rendered services – due to absence of economic justification and/or document support of its expenses on payments for rendered services;
- challenge the recoverability of income VAT on purchased services and charge additional VAT.

Please take into account that the possibility to pay pharmacies for rendered services related to **medical devices** is ambiguous. Russian tax authorities and courts may apply the conservative approach and state that such payments contradict Russian industrial legislation and challenge the deductibility of relevant expenses.

How can BST help?

Our professionals:

- perform analysis of documents sustaining company's expenses on bonuses/payments for rendered services for the purpose of profits tax/VAT;
- provide recommendations on mitigation of outlined tax risks related to stimulation payments to pharmacies.

Stimulation Payments to Pharmacies (2/2)

Restriction of the amount of stimulation payments

Currently the Russian State Duma is considering implementing two amendments[(21)] to the Federal Law No. 61-FZ dated 12 April 2010 “On Circulation of Medicines”, which will introduce the following restrictions towards stimulation payments for pharmacies:

1. limitations of the total amount of remuneration under service agreements on promotion of medicines paid by manufacturers of medicines to pharmacies – 5% of medicines purchase price (as per Draft Federal Law No. 912246-7) / total amount of bonuses and/or payments for rendered services shall not exceed 5% from medicines purchase price (as per Draft Federal Law No. 923315-7);
2. introduction of prohibition of particular types of stimulation payments, including: remuneration for the purchase of VED-listed medicines, payment for the right to supply medicines to pharmacies, change their assortment (as per Draft Federal Law No. 923315-7);
3. restriction of the right of entities engaged in the sale of medicines and medical devices to purchase/lease additional space for retail trade if the volume of goods sold by such entities exceeds 20% of the volume of goods sold within the borders of one federal city, municipal district or urban district.

In case the abovementioned draft federal laws are adopted with the current wordings, it may have a negative impact not only on manufacturers of medicines and medical devices, who will be forced to change the effective structure of interaction with pharmacies, but also on consumers due to possible negative impact on the availability of medicines and medical devices in certain regions of Russia.

How can BST help?

We recommend monitoring the status of the abovementioned draft federal laws and amendments made (in case of any) to their provisions.

Our professionals, in their turn, my assist with development of options for the change of current structure of stimulation of pharmacies for the purpose of meeting the requirements to be set by the provisions of the draft federal laws and mitigation of risk of administrative liability in case of not meeting the abovementioned requirements.

(21) Draft Federal Law No. 912246-7, currently adopted in the first hearing (URL: https://sozd.duma.gov.ru/bill/912246-7); Draft Federal Law No. 923315-7, currently pending for the first hearing (URL: https://sozd.duma.gov.ru/bill/923315-7).

Payments to Health Care Professionals

Russian industrial legislation states that health care professionals ("**HCPs**") and heads of medical organizations are not allowed to accept gifts or money from companies that develop, produce or sell medicines or medical devices as well as from pharmacies[22].

However, there are certain exemptions from the rule above: HCPs are allowed to receive compensation in case it is related to their:

1. contracts for conduction of clinical trials of medicines;
2. contracts for conduction of clinical trials of medical devices;
3. carrying out scientific[23] or educational activities .

As a result, Russian tax authorities may challenge the scientific or educational nature of the activities performed by HCPs and consequently challenge the company's expenses on payments to HCPs. Moreover, we also pay your attention that the breach of rules on cooperation with HCPs may result not only in tax risks, but also criminal liability of companies paying to HCPs..

How can BST help?

- structuring of payments to HCPs under contracts for scientific and educational activities for the purpose of profits tax and VAT;
- analysis of tax implications related to personal income tax and social contributions with respect to the company's travel, accommodation and other expenses borne under contracts for scientific and educational activities with HCPs;
- consulting services related to providing HCPs with product samples and promotional materials taking into account both the provisions of tax legislation and compliance requirements.

22) Federal Law No. 323-FZ dated 21 November 2011 "On the Basics of Public Health Protection in the Russian Federation"; Federal Law No. 61-FZ dated 12 April 2010 "On Circulation of Medicines".
(23) Federal Law No. 127-FZ dated 23 August 1996 "On Science and State Scientific and Technical Policy".

Advertising (1/2)

Russian advertising legislation[24] contains general requirements towards the advertising of both OTC and Rx medicines and prohibits the advertising of Rx medicines unless certain criteria are met (e.g., Rx medicines may be advertised upon holding medical and pharmaceutical exhibitions, seminars, conferences and other similar events as well as in printed press intended for HCPs).

General requirements to advertising of OTC and Rx medicines:

- ads should not address the minors;
- ads should not contain a reference to specific cases when someone has been cured;
- ads should not assist in causing a healthy person to gain the impression that he/she should use the object of advertising;
- ads should not create the impression that there is no need to visit a doctor;
- ads should not contain the assertion that the safety and/or effectiveness of the object of advertising are guaranteed by its natural origin;
- other.

The abovementioned requirements are also applicable to advertising of medical devices.
As for advertising of nutritional supplements, its requirements slightly differ from those applicable for medicines and medical devices: e.g., they include prohibition of motivation to give up healthy eating, of expression of gratitude by individuals in connection with the use of such nutritional supplements, etc. Moreover, advertising of nutritional supplements in each case shall be followed by a disclaimer stating that such nutritional supplements are not medicines [25].

Rationing advertising expenses

Presidential Decree No. 585 of 08.08.2023 “On Suspension by the Russian Federation of Certain Provisions of Double Tax Treaties” (the “PD No. 585”) suspended certain provisions of Double Tax Treaties, including Art. 24 “on the Prevention of Tax Discrimination”.
On the basis of the PP RF No. 719 and Russian Tax Code (the “RTC”) Companies that have not previously rationed advertising expenses in accordance with the DDT should ration advertising expenses in accordance with para. 4 of art. 264 of the RTC.

24) Federal Law No. 38-FZ dated 13 March 2006 “On Advertising” (art. 25).
(25) Federal Law No. 38-FZ dated 13 March 2006 “On Advertising” (art. 24).

Advertising (2/2)

Marketing services on the promotion of pharmaceuticals

According to current practice, Russian pharmaceutical companies provide marketing services on the promotion of pharmaceuticals to a foreign company of the group.

In accordance with art. 148 of the RTC, marketing services are taxed on a customer basis, i.e. in this case marketing services are not subject to VAT for Russian pharmaceutical company.

According to current court practice (Resolution of the Moscow District Arbitration Court of October 19, 2023 in case No. A40-218059/2022 – the case of Novamedica) tax authority could change qualification of expenses on promotion of pharmaceuticals from marketing to informational and other type of services that taxed on seller basis and charge additional VAT in accordance with art. 148 of the RTC.

How can BST help?

Our BST professionals provide tax and legal following consulting services

1. analysis of whether a company's advertising of medicines, medical devices and nutritional supplements is in compliance with Russian legislation taking into consideration positions of Russian court and administrative practice;
2. analysis of whether tax requirements are met upon treatment of expenses on advertising as profits tax deductible;
3. analysis of the description of each of the advertising expenses and provision of our recommendations whether these expenses are subject to rationing according to the requirements of para. 4, art. 264 of the Tax Code of the Russian Federation, as well as court and administrative practice;
4. confirmation of marketing qualification of expenses on promotion of pharmaceuticals by preparing necessary documents and structuring the company's marketing expenses.

Online Sale of Medicines

Online Sale of Medicines

Following the escalation of the COVID-19 pandemic in Russia in March 2020, the President signed a decree permitting online sale of medicines. Subsequently, the relevant federal law entered into force in April 2020. Finally, in May 2020 rules on online sale of medicines became effective[(26)].

Current rules of online sale of medicines envisage that only OTC medicines may be sold online (Rx medicines, narcotic medicines, psychedelic medicines and medicines consisting of more than 25% ethanol may be sold exclusively via offline sale channels).

However, a draft law permitting online sale of Rx medicines as part of an experiment to be conducted from 1 March 2023 to 1 March 2026 in Moscow, Moscow Oblast and Belgorod Oblast is currently being reviewed by the Russian State Duma.

Obtainment of the authorization issued by the Roszdravnadzor is essential for the purpose of carrying out online sale of medicines.

Online sale of medicines may be carried out by either pharmacies (except for sole proprietors) that have had for at least one year a pharmaceutical license for retail sale of medicines, or by marketplaces (e.g., Wildberries, Ozon, Yandex.Market, etc.) in case an agreement between such pharmacy and a marketplace is concluded.

The following requirements are set towards pharmacies for the purpose of carrying out online sale of medicines:

1. existence of equipped space for storage of made orders in accordance with the GS&TP;
2. existence of a web-site;
3. existence of an own courier service that has equipment providing for maintenance of necessary temperature regime for the purpose of delivery of particular medicines or an agreement with other persons carrying out delivery with usage of such equipment;
4. existence of an electronic transfer of funds system and/or mobile payment kiosks intended for making electronic transfer of funds, including with banking cards in the place of rendering of services.

Online sale of medical devices and nutritional supplements is also permitted in Russia provided that it is carried out by pharmacies and sole proprietors, which have a pharmaceutical license[(27)]. No authorization is needed for online sale of such goods.

(26) Resolution of the Government of the Russian Federation No. 697 dated 20 May 2020.
(27) Federal Law No. 61-FZ dated 12 April 2010 "On Circulation of Medicines" (art. 55 p. 7).

How can BST help?

Our BST professionals can provide assistance upon interaction with the Roszdravnadzor for the purpose of obtaining the authorization on online sale of medicines.

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