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2023: Legislative developments impacting the pharmaceutical and medical device industries

Overview by the Life Sciences & Healthcare sector group at SEAMLESS Legal

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In recent years, business in Russia has been affected by sweeping political and economic events. Some companies have left the Russian market, others have changed the format of their presence, and others have seen new opportunities.

The regulator has piloted, introduced and cancelled various incentives, both positive and negative. Such measures were often either a return to long-forgotten regulatory approaches or completely new solutions.

By early 2024, the situation has relatively stabilised. The government has developed a new approach to regulating and controlling the industry, and many of its players already have more or less sustainable plans for the future.

However, it is clear that the healthcare industry has not yet met all the challenges. It still has a long and winding road to go. To make it easier for you to navigate this journey, below is our overview of the main legal changes in the pharmaceutical and medical devices sector in 2023.

Regulatory easing

The events of 2022 and the imposition of international sanctions against Russia have become a reason for many companies to revise their plans for the Russian market. As a result, supplies of certain drugs and medical devices were reduced, and the Russian regulator responded by introducing various support measures for importers and local manufacturers in 2022 and 2023. Many such measures remain in effect in 2024.

Fast-track registration of analogue drugs

Until the end of 2024, in the event of [a risk of] shortage due to sanctions, a therapeutic analogue drug may be registered under the fast-track procedure approved by Russian Government Decree No. 593 dated 5 April 2022. After such registration, the temporary marketing authorisation will be issued, valid until the end of 2024 and extendible up to the end of 2025.

Importing drugs in foreign packaging

As a further measure to ensure the availability of essential foreign drugs on the market, the legislators have allowed these to be imported in foreign packaging (Article 47(3.2) of the Federal Law "On the Circulation of Medicines"; "**FZ-61**"), subject to the following conditions:

- the drug imported in foreign packaging meets the applicable requirements for its registration in Russia, save for the requirements on primary and secondary packaging;
- the drug is in short supply or there is a risk of a shortage due to sanctions;
- the multi-authority commission has issued an opinion that a particular series (batch) of the drug can be marketed in foreign packaging;

- a self-adhesive label containing information about the drug in the Russian language is affixed to the consumer packaging of the imported drug;

- each packaging is accompanied by a Russian-language translation of the instruction for use approved by the competent authority of the country of manufacture or the country of the marketing authorisation holder.

Importantly, this does not constitute legalisation of parallel imports of drugs. When importing a drug in foreign packaging, only public law liability for the circulation of inappropriate products should be excluded. For example, a company will not be fined because the foreign packaging of an imported drug is not in conformity with the Russian registration dossier.

However, the importer is not exempt from any possible private law liability to the right holder. For instance, the owner of a trademark placed on the packaging of a drug imported into Russia may formally claim compensation from the importer in connection with the unauthorised importation of the drug.

Circulation of unregistered drugs

The Russian Government allows batches (series) of an unregistered drug having the INN analogue registered in Russia to be circulated in Russia subject to the permission of the Russian Ministry of Health (hereinafter – "**Minzdrav**"), provided that:

- the drug is in short supply or there is a risk of a shortage due to sanctions;

- the multi-authority commission has issued the opinion on the possibility of issuance of the permission for temporary circulation;

- the drug is authorised for medical use in a foreign country;

- the consumer packaging is designed in the language of the country of manufacture and bears a self-adhesive label containing information in Russian;

- each packaging is accompanied by a Russian-language translation of the instruction for use approved by the competent authority of the country of manufacture or the country of the marketing authorisation holder.

Notably, the federal law contains no such exemption from the mandatory registration requirement (Article 47(2) of FZ-61). However, we are not aware of any cases in which this inaccuracy would cause practical problems.

The measure is temporary – permits will be issued until the end of this year. The permit itself is also issued for the same period. At the same time, in accordance with Russian Government Decree No. 2269 dated 23 December 2023, all previously issued permits that expired or were expiring in 2023 are also extended until the end of 2024.

Fast-track registration of medical devices in short supply

Certain types of medical devices can also be registered under a fast-track procedure if there is a shortage of such devices. According to the specifics of circulation approved by Government Decree No. 552 dated 1 April 2022, the list of types of medical devices eligible for fast-track registration is to be drawn up by a special multi-authority commission.

The work of the multi-authority commission formally ceased in autumn 2023. However, in December it was resumed in accordance with Roszdravnadzor Order No. 8003 dated 13 November 2023. The commission is expected to continue considering proposals to list devices until at least the end of 2024.

Use of non-original components and accessories in the maintenance of medical devices

From 7 January 2023, amendments to the specifics of circulation of medical devices approved by Government Decree No. 552 dated 1 April 2022 came into force, according to which any components and accessories that are not envisaged in the manufacturer's documentation may be used in the maintenance of devices in short supply.

The use of such components and accessories is permitted subject to the opinion of the All-Russia Research and Testing Institute of Medical Technology (hereinafter – the "**Institute**"). In order to obtain such an opinion, it is necessary to confirm the safety of the joint use of parts based on the following tests (studies):

- technical;
- toxicological (if applicable);
- clinical (if requested by the results of the above).

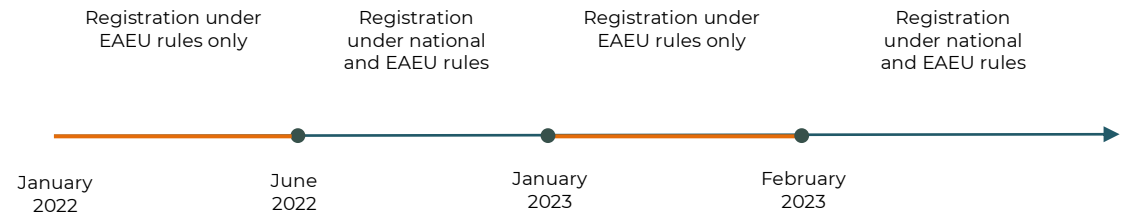
Extension of marketing authorisations

Government Decree No. 2269 dated 23 December 2023 extends for 12 months the validity of marketing authorisations expiring in 2024.

Extended and updated national procedure for registration of medical devices

Extension of the national registration procedure

In February 2023, it was possible to have medical devices registered under both the national procedure and the EAEU rules. According to the latest changes, this possibility will remain at least until the end of 2025.



This is not the first extension of the national procedure. As last time, the procedure is extended already after the expiry of the periods for which national registration was allowed.

We recall that in 2022, due to the "desynchronised" actions of the Eurasian Economic Commission and national regulators, the registration under national rules was unavailable for about six months.

Planned change in the national registration rules

The new rules for the registration of medical devices have been drafted. Among other things, the document provides for fast-track registration of in-vitro medical devices, medical software and domestic medical devices.

As a general rule, if the registration requires clinical trials involving human participants, it will be carried out in two stages and will take up to 50 business days from the date of the decision of the Federal Service for Surveillance in Healthcare (hereinafter – "**Roszdravnadzor**") to initiate the registration.

If human trials are not required, the registration will be a one-step process and may take 32 to 33 business days.

A special registration procedure is envisaged for domestic medical devices. Domestically manufactured medical devices will be qualified as such provided that they have undergone all necessary trials (except for clinical ones) at the Institute and clinical trials at a research centre authorised by Minzdrav.

By the end of 2025, domestic devices can be registered in one step by applying to the Institute for quality, efficiency and safety expert examination which will take 25 business days. The application shall be accompanied by documents evidencing the results of clinical and other necessary trials. If a positive expert opinion is issued by the Institute and accepted by Roszdravnadzor, an application can be submitted for registering the medical device, that will be considered within 5 business days.

The draft also provides that the fact of state registration of a medical device will be confirmed by a register entry rather than by a marketing authorisation (as is currently the case under the national registration and EAEU rules).

Simpler EAEU requirements for drug registration

In 2023, many amendments were made to the Registration Rules approved by Eurasian Economic Commission Council Decision No. 78 dated 3 November 2016. The changes are not fundamental and are mainly aimed at facilitating certain aspects of registration (re-registration) of drugs at the EAEU level. Among them, the following can be highlighted:

Classification of comments on the dossier

Comments on the dossier submitted for registration are now classed into critical ones (involving an unacceptable risk) and non-critical ones (involving a deviation from the requirements that cannot result in a risk of harm to health).

Critical comments in the dossier make the registration impossible until they are rectified. Non-critical comments, on the other hand, can either have the same effect, or affect the conditions of registration (i.e. allow it only if specifically defined requirements, such as those for instructions for use and labelling, are met), or result in no consequences.

Bringing dossiers into line with EAEU requirements

There are a number of new rules for the alignment procedure, which should make the process clearer and more transparent.

Among other things, special requirements now apply to registration dossiers to be brought into line with EAEU requirements, which detail the design of the various modules of the dossier and arrange the documents to be included in the modules. The rules for making changes to the dossier along with the alignment have also been optimised.

Use of national GMP certificate

When applying for registration until the end of 2024, instead of the EAEU GMP certificate, it will be possible to submit a national certificate together with documents according to the approved list, provided the EAEU GMP certificate cannot be provided. The documents to be attached to the application together with national GMP certificate include copies of the recent inspection report, information on the results of all inspections and information on complaints regarding the quality of drugs produced at the production site for the past three years; copies of the main dossier of the production site, etc.).

New compulsory licence

In 2022, Russian officials reminded foreign companies announcing the reduction of their business in Russia that there is a compulsory licensing mechanism. By this they meant the right of the Russian Government to decide, in case of emergency (a shortage of a drug can be deemed as such), to use an invention without the patentee's consent. This allows a Government-appointed Russian company to use another party's invention protected by patent and produce the drug without the patent owner's permission.

In 2023, this risk was realised: two Russian pharmaceutical companies received permission to manufacture pharmaceuticals, the patents for which are owned by a foreign entity and protect the drug Semaglutide (the trade name of the original drug is Ozempic). This compulsory license will be in effect until the end of 2024.

Thus, even in 2024, the risk of compulsory licensing for foreign pharmaceutical manufacturers should be recognised as real.

At the same time, patent owners from "unfriendly" countries cannot expect compensation for using their invention under a compulsory licence – for them it is 0% of the actual revenue.

For patent holders from other countries, the amount of compensation remains the same, namely 0.5% of actual revenue.

Amendments to the Federal Law "On the circulation of medicines"

On 30 January of this year the federal law on amendments to FZ-61 has been published. Significant part of amendments will come into force in autumn of this year or later. The main purpose of the changes is harmonisation with the EAEU regulations governing the circulation of medicines. Among the most significant changes are the following:

- absence of a drug in circulation in Russia for 3 or more years will not be ground for cancelling its state registration;
- changes in procedure of putting drugs in circulation;
- Minzdrav will provide Roszdravnadzor with detailed information from the registration dossier of a drug in order for the surveillance authority to carry out its functions;
- abandoning the mechanism of suspension of a drug use.

Problems with importing sanctioned goods

New sanctions packages of "unfriendly" states regularly expand the list of goods, the supply of which to Russia requires complying with a permitting procedure – obtaining a so-called

"export licence" from the competent authority of a relevant state (BAFA in Germany, BIS in the USA, etc.).

When deciding whether to issue an export licence, the competent authority must ensure that the delivery of goods will not violate any sanctions restrictions, in particular that the goods will not be used for military purposes. In many countries, the procedure is lengthy and non-transparent: application processing is often delayed, and the applicant is frequently unable to follow up on the status of the matter or provide additional information. Consideration of the application may take several months or more, after which the applicant may receive a refusal to approve the supply, which is extremely problematic to challenge or appeal.

At the moment, the imperfect mechanism for issuing export licences in many countries creates problems for imports into Russia even of those goods whose delivery is not formally banned under sanctions regulations.

Export restrictions on equipment

Government Decrees Nos. 311, 312 and 313 dated 9 March 2022 have imposed broad export restrictions affecting, among other things, laboratory and industrial equipment. The restrictions have been extended until the end of 2025.

Depending on the type of goods and the country of destination, the Decrees either establish a blanket ban on exports or require that a special permit be obtained from the Russian Government or a regulatory or surveillance authority.

Importantly, for certain types of products export authorisation may need to be obtained from several governmental authorities, sometimes those that have little involvement in the regulation of medical devices. In our practice we encountered a case where the export of a medical device required permits from both the Ministry of Industry and Trade and the Ministry of Natural Resources and the Environment.

Off-label prescription has been regulated

On 27 October 2023, the Government adopted Decree No. 1799 approving new requirements for the administration of drugs under indications that are not specified in their instructions for use. Such use of drugs is also referred to in the industry as "off-label".

The Decree will come into force on 1 September 2024. Off-label drug use can be included in the standards of medical care for children as well as clinical recommendations if the relevant drug is registered in Russia and meets at least one of two criteria:

- the effectiveness and safety of off-label drug use are confirmed by data from scientific research and/or descriptions of clinical cases published in scientific publications listed in the Russian Science Citation Index, Scopus or Web of Science;

- an indication of the effectiveness and safety of off-label drug use is supported by recommendations adopted by international professional organisations.

In the initial version that should have taken effect, the rules required that drug safety and effectiveness is proven through clinical trials and that the drug meets two conditions at the same time and is of higher effectiveness or safety compared to drugs used on-label. Thus, the final wording has been significantly relaxed.

The idea of including off-label use in the standards of medical care for children and clinical recommendations has been reflected in the legislation for quite some time. The lack of requirements for the drugs to be used off-label was the final obstacle to implementing this idea.

These amendments should increase the number of off-label prescriptions and make the relevant drugs more popular on the Russian market.

Product labelling

In the health sector, the number of products subject to labelling has expanded. In addition to mandatory labelling of drugs, mandatory labelling of certain types of medical devices was introduced in 2023, and some assistive devices will be labelled on a pilot basis.

Mandatory labelling of medical devices

On 1 September 2023, Government Decrees No. 894 and No. 885 dated 31 May 2023 came into force, establishing new rules for mandatory labelling of the following groups of medical devices (the "**Rules**"):

(A) air purifiers, orthopaedic insoles and footwear;

(B) wheelchairs;

(C) hearing aids, coronary stents, CT scanners and devices used for incontinence.

From 1 October 2023, group (A) and (B) medical devices registered in Russia will be prohibited from being marketed if they bear no Data Matrix identification code and if no information is reported to the monitoring system that they have been labelled and put on the market. From 1 March 2024, a similar ban will apply to group (C) medical devices.

It will not be necessary to amend the registration dossiers of medical devices in connection with applying a code on their packaging.

Labelling codes will be generated by the monitoring system. In order to receive them, a business entity has to be registered in the system and the devices to be labelled – in the National Catalogue of Labelled Goods.

A manufacturer or importer has to file with the system an application for obtaining labelling codes together with necessary information. If the application is approved, the codes will be received by the issuance registration device. The business entity may instruct a service provider to further transform them into means of identification and apply them on the packaging. What is most important is that the labelling should be applied to:

- devices manufactured in Russia – before they are put on the market;
- devices manufactured in the EAEU – before they are moved across the Russian border;
- devices manufactured outside the EAEU – before they are subjected to the customs procedures of release for domestic consumption or re-import.

It should be noted that the concept of putting on the market under the Rules has a specific content. Whether a particular dealing with the goods constitutes "putting on the market" depends on a number of factors. For example, the place of production, the type of transaction and its specifics, and the purpose of purchasing the goods.

From 1 September 2024, information on the withdrawal of medical devices of all groups from circulation and on the circulation of group (B) medical devices will also have to be reported to the system. Information on the circulation of devices in groups (A) and (C) will have to be submitted to the system from 1 September 2025.

Experiment on labelling of certain types of assistive devices

In autumn 2023, Russia launched an experiment on labelling certain types of assistive devices, namely:

- walking-sticks, supports, crutches, handrails;
- parts and accessories of prosthetic devices; functional units and orthoses;
- pressure relief mattresses and pillows;
- special devices for excretory disorders (urine and colostomy bags);
- armchairs with sanitary equipment.

According to Government Decree No. 1632 dated 3 October 2023, the labelling experiment will last until 31 August 2024. However, no guidance notes on its implementation or other necessary regulatory documents have been adopted yet.

Pharmaceutical substance traceability experiment

On 29 December, Government Decree No. 2261 dated 22 December 2023 launched a pharmaceutical substance traceability experiment. It is open to drug manufacturers that have fully or partially localised production in Russia or the EAEU. As part of the experiment, information on all stages of production of drugs will be transmitted to the system, which will make it possible to check and confirm the level of localisation.

We remind that the production localisation level plays a key role in the application of the "third odd one out" mechanism in public procurement, as well as a number of other measures of state support for domestic manufacturers. Thus, the experiment will help to improve measures aimed at developing full-cycle production of pharmaceuticals in Russia.

Substances such as menthol, salicylic acid and antibiotics among others are included in the experiment. The scheduled plan of the testing and guidance notes on its implementation should be in place by 10 February 2024.

Cosmetics and household chemicals labelling experiment

On 15 January 2024, an experiment on labelling of perfumes, cosmetics and household chemicals was launched. According to Government Decree No. 2405 dated 29 December 2023, it will last until 28 February 2025.

The objectives of the experiment are (1) to test the labelling mechanism for perfumes, cosmetics and household chemicals; and (2) to prepare market participants for the introduction of mandatory labelling. The following products will be affected by the experiment:

- cosmetic or make-up products;
- skin care products, including sun block or tanning products;
- manicure or pedicure products;
- hair care products;
- oral or dental hygiene products;
- shaving products;
- deodorants for personal use;
- bath formulations;
- hair removal products;
- indoor deodorants;
- soap;
- detergents and cleaning products.

Participation in the experiment is on a voluntary basis. Possible participants include manufacturers and importers of the above products, as well as wholesalers and retailers.

To join the experiment, it is necessary to:

1. Submit an electronic application for joining the experiment.
2. Register in the labelling system, for manufacturers – fill in the cards of the products they produce.
3. Acquire, configure and commission equipment and software designed for applying and reading labelling codes and transmitting information to the labelling system. Labelling codes will be issued free of charge.

Information on where to apply and more detailed information on the participants' roles will be reflected in the guidance notes to be approved by the Ministry of Industry and Trade.

Experiment on online trade in Rx drugs

On 1 March 2023, three regions (Moscow, Moscow Region and Belgorod Region) launched an experiment for selling Rx drugs remotely. Its rules are set out in Article 55.1 of FZ-61 and Government Decree No. 292 dated 22 February 2023.

To join the experiment, a pharmacy needs to apply to Roszdravnadzor of the region included in the experiment.

Requirements for the candidate include having a connection to the Uniform State Health Information System, equipment for proper storage and transport of ordered goods, technical means for payment and (if applicable) a contract with an aggregator. The criteria and procedure for selecting pharmacies are regulated in more detail at the level of the three regions mentioned above.

One can find out whether their application is approved from the updated list of participating pharmacies on the website of the regional Minzdrav.

A pharmacy that has been selected for the experiment shall apply to the federal Roszdravnadzor for authorisation to carry out retail sales of drugs remotely. The application will be considered within five business days. Once the authorisation has been obtained (and included in the list of authorisations on the Roszdravnadzor website), one can start trading.

The experiment does not yet allow acquiring drugs on a preferential basis, but proposals to give the relevant categories of citizens such an opportunity have already been put forward. Perhaps in 2024 they will be implemented.

Online ad labelling

Certain labelling requirements for online advertising appeared as early as 2022, but the system became fully operational in 2023. Online advertisements must now be accompanied by an identifier, labelled “advertisement” and contain a reference to the advertiser or a website disclosing information about the advertiser.

As a general rule, all participants in the advertising chain (advertiser, advertising distributor, advertising system operator) must report on advertising they distribute, to the Unified Internet Advertising Register through advertising data operators.

Labelling rules for online advertising are uniform across all industries, but for the pharmaceutical sector their application has been complicated by the long-standing problem of promoting Rx drugs.

According to Article 24(8) of the Federal Law “On Advertising”, advertising of Rx drugs is allowed only at medical/pharmaceutical events and in specialised printed media. However, the Federal Antimonopoly Service has consistently adhered to a literal interpretation of this restriction and does not recognise various internet resources for healthcare professionals as a permissible platform for promoting a Rx drug.

At the same time, such internet resources in practice often contain materials aimed at promoting drugs. The administrators of such resources generally take a position that they are not subject to advertising legislation due to the fact that the information on such websites is not addressed to general public (which is one of the mandatory features of advertising), but to a closed list of users (registered doctors and pharmacists).

As an additional justification for this approach, registration on an online resource may require the provision of a diploma confirming medical or pharmaceutical education, passing a short professional test, etc.

Such position is debatable and remained in the "grey" zone for a long time. The regulatory authority rarely enquired about the content of websites for health professionals.

However, owners of such resources now have a choice to make: either label materials on Rx drugs as "advertising" ones, thus recognising a violation of Article 24(8) of the Federal Law "On Advertising"; or ignore the new labelling requirement, risking a fine not only for advertising Rx drugs in an inappropriate place, but also for the lack of labelling. At the moment, most specialised online resources choose the second option.

Government control

On the one hand, amid the COVID-19 pandemic and then international sanctions, the Government has relaxed its control over business. The most significant relaxation was the moratorium on routine inspections, which last March was extended for most of the industry until 2030.

On the other hand, legislation continues to be amended, affecting businesses even under the moratorium. Due to the transition to a risk-based control model, the number of risk indicators that can lead to an unscheduled inspection is expanding, and the approach to preventing violations is changing.

Expanded list of risk indicators for the circulation of medical devices

Until 2 September 2023, the only indicator of the risk of violating mandatory requirements in the circulation of medical devices was a twofold or greater increase in the number of documents on the results of clinical trials issued by a healthcare organisation in a calendar year compared to the previous year. Now two more indicators have been added:

1. During the year, Roszdravnadzor receives an application for a licence (amendment of the register of licences) for the maintenance of medical devices from an entity engaged in such activities:
    - using the equipment held and used by a licensee from another region; or
    - in the premises held and used by another licensee who has not declared a change of address of the place of business or its cessation.
2. A licence applicant (licensee) has an employee engaged in the maintenance of medical devices who, within a calendar year, entered into an employment contract with another licensee from another Russian region, if as a result the two places of work of such an employee are located in regions that do not share a common border.

Thus, while previously the risk indicators were actually used only in the control over clinics conducting clinical trials, they are now also becoming relevant for companies engaged in the maintenance of medical devices.

The risk indicators for drug manufacture have been changed

In August 2023, the risk indicators for drug manufacture were updated. They now look as follows:

1. Three or more withdrawals from circulation of any series / batches of a drug which showed non-compliance with quality requirements during testing, within a quarter from a manufacturer.

2. Subjecting a manufacturer's drug to skip batch testing.

Information from Roszdravnadzor's Automated Information System is used to monitor the indicators.

A new format of preventive visits

A preventive visit takes the form of a conversation with an inspector and involves advising the supervised person on compliance with mandatory requirements. Such visits are made subject to company's consent.

As a general rule, no prescriptive orders are issued as a result of a preventive visit and the visit can be turned down (even if the visit is initiated by the supervisory authority). For example, in 2023 many manufacturers of medical devices received warnings from Roszdravnadzor along with a proposal to conduct a preventive visit. Such letters came from the state authority as a response to company reports as part of monitoring the safety of medical devices.

In 2023, several exceptions were added to the rule regarding the voluntary nature of a preventive visit and non-issuance of prescriptive orders. One of them is where a visit is commissioned by the President, the Prime Minister or his/her deputies. In this case, the visit cannot be turned down and will take the form of a curtailed on-site inspection. Sampling, request for documents, inspection, testing, instrument-aided survey and expert examination are allowed. The visit may result in the issuance of a prescriptive order.

Conclusions

One of the outcomes of 2023 could be a partial return to certainty. The market for healthcare products has relatively stabilised. Worst fears about inventory shortage of drugs and medical devices have not materialised and the regulator's actions have become more predictable.

Nevertheless, many of the problems for foreign companies in Russia that arose in 2022-2023 remain relevant: expanded lists of sanctioned goods and difficulties in obtaining export licences, corporate restrictions on the sale of Russian business, reactivation of the compulsory licensing mechanism, etc.

New unexpected changes in the economic, political and legislative landscapes cannot be ruled out this year. But hopefully, the industry will continue to successfully adjust to regulatory changes, overcome difficulties with logistics and international settlements. It is also hoped that

obtaining export licences and other permitting procedures due to sanctions pressure will become more transparent and predictable.

Our team is always ready to provide full legal support on any issues associated with doing business in Russia.

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Annex. References

1. Decision of the EEC Council No. 78 dated 03.11.2016 “On the Rules for Registration and Examination of Medicines”

2. Federal Law No. 61-FZ dated 12.04.2010 “On the Circulation of Medicines”

3. Federal Law No. 38-FZ dated 13.03.2006 “On Advertising”

4. Decree of the Government of the Russian Federation No. 311 dated 09.03.2022 “On Measures for Implementation of the Order of the President of the Russian Federation No. 100 dated 8 March 2022”

5. Decree of the Government of the Russian Federation No. 312 dated 09.03.2022 “On Temporary Introduction of a Permissive Procedure for the Export of Certain Types of Goods out of the Russian Federation”

6. Decree of the Government of the Russian Federation No. 313 dated 09.03.2022 “On Measures for Implementation of the Order of the President of the Russian Federation No. 100 dated 8 March 2022”

7. Decree of the Government of the Russian Federation No. 552 dated 01.04.2022 “On Approval of the Specifics of Circulation, Including the Specifics of State Registration, of Medical Devices in case of Their Shortage or Risk of Shortage in Connection with the Restrictive Economic Measures against the Russian Federation”

8. Decree of the Government of the Russian Federation No. 593 dated 05.04.2022 “On the Specifics of the Circulation of Medicines in case of Their Shortage or Risk of Shortage in Connection with the Restrictive Economic Measures against the Russian Federation”

9. Decree of the Government of the Russian Federation No. 292 dated 22.02.2023 "On Approval of the Regulation on the Procedure for Conducting an Experiment on the Retail Trade of Prescription Medicines by Remote Means"

10. Decree of the Government of the Russian Federation No. 885 dated 31.05.2023 “On Approval of the Rules for Labelling Wheelchairs with Means of Identification and the Specifics of the Implementation of the State Information System for Monitoring the Circulation of Goods Subject to Mandatory Labelling in Relation to Wheelchairs”

11. Decree of the Government of the Russian Federation No. 894 dated 31.05.2023 “On Approval of the Rules for Labelling Certain Types of Medical Devices by Means of Identification and the Specifics of the Implementation of the State Information System for Monitoring the Circulation of Goods Subject to Mandatory Labelling in Relation to Certain Types of Medical Devices”

12. Decree of the Government of the Russian Federation No. 1632 dated 03.10.2023 “On Conducting an Experiment on Labelling Certain Types of Assistive Devices with Means of Identification on the Territory of the Russian Federation”

13. Decree of the Government of the Russian Federation No. 1799 dated 27.10.2023 "On Approval of the Requirements for a Medicine Administered under Indications that are Not Specified in Its Instruction for Use Which is Allowed for Inclusion into the Standards of Medical Care for Children and Clinical Guidelines"

14. Decree of the Government of the Russian Federation No. 2261 dated 22.12.2023 "On Conducting an Experiment on the Traceability of Medicines and Raw Materials Used for the Production of Medicines on the Territory of the Russian Federation"

15. Decree of the Government of the Russian Federation No. 2269 dated 23.12.2023 "On Amendments to the Decree of the Government of the Russian Federation No. 353 dated 12 March 2022"

16. Decree of the Government of the Russian Federation No. 2405 dated 29.12.2023 "On Conducting an Experiment on Labelling Certain Types of Perfumery and Cosmetic Products and Household Chemicals on the Territory of the Russian Federation"

17. Order of Roszdravnadzor No. 8003 dated 13.11.2023 "On the Establishment of the Interdepartmental Commission for the Formation of the List of Types of Medical Devices Subject to Circulation in Accordance with the Specifics Approved by the Decree of the Government of the Russian Federation No. 552 dated 1 April 2022 and Approval of Its Regulation"