22. The Pharmaceuticals and Healthcare Industry

22.1 Legal Framework

The protection of citizens’ health is one of the principles of the constitutional system of Russia declared by the Russian Constitution, and the Russian healthcare system is built around this principle.

The formal basis of the Russian healthcare system is laid out in Federal Law No. 323-FZ “On the Fundamentals of Citizens’ Health Protection in the Russian Federation” (the “Fundamentals”), which completely replaced its predecessor, “Fundamentals of the Legislation of the Russian Federation on Protection of Citizens’ Health”, No. 5487-1, dated 22 July 1993, from 1 January 2012. The Fundamentals, some provisions of which are yet to come into force, standardize healthcare and significantly restrict the marketing and promotional activities of pharmaceutical companies. Federal Law No. 178-FZ “On State Social Care”, dated 17 July 1999, as amended (the “Social Care Law”) is also an important legislative act regulating the Russian healthcare system. The main legislative act specifically governing the pharmaceutical market in Russia is Federal Law No. 61-FZ “On the Circulation of Medicines”, dated 12 April 2010, as amended (the “Law on Circulation of Medicines”). The Law on Circulation of Medicines was significantly amended at the very end of 2014 and a bulk of the amendments has been in force since the beginning of 2016.

The amended Law on Circulation of Medicines now most importantly, (i) has limited data exclusivity protection compared to the prior version, (ii) reinstates the grace period for medicinal preparations which recently had their registration dossier changed, (iii) lays the groundwork for revision of state regulation of prices, (iv) introduces new regulations on biological/biosimilar and orphan medicinal preparations, (v) establishes the interchangeability of medicinal preparations.
As regards medical devices, to date, only three articles in the Fundamentals specifically regulate them. A draft law on the circulation of medical devices is still being prepared.


It is also worth mentioning that the harmonization of the pharmaceuticals and medical device legislation in the Eurasian Economic Union (“EAEU”) is ongoing. The basic documents for the harmonization of the EAEU pharmaceuticals and medical device legislation are: the Treaty on Establishment of EAEU, the Agreement on Common Principles and Rules for the Treatment of Medicinal Preparations within EAEU dated December 23, 2014 and the Agreement on Common Principles and Rules for the Treatment of Medical Devices (Devices for Medical Purposes and Medical Equipment) within EAEU dated December 23, 2014 (the “Agreements”).

These documents provide for the establishment of a common market of medicinal preparations and medical devices within the EAEU and free flow of medicinal preparations and medical devices starting from the date when each EAEU member state notifies the depository of the Agreements of the fact that it has performed the internal procedures necessary for the Agreements to enter into force. This has not happened as of the date of this guide.
The Agreement on Common Principles and Rules for the Treatment of Medicinal Preparations within the EAEU provides for a transitional period that should start on January 1, 2016 and expire on December 31, 2025.

The Agreement on Common Principles and Rules for the Treatment of Medical Devices (Devices for Medical Purposes and Medical Equipment) within the EAEU dated December 23, 2014 provides for a transitional period that should start on January 1, 2016 and expire on December 31, 2021.

Therefore, the unified market of medicinal preparations should finally come into effect only in 2026 and the unified market of medical devices should be fully effective from 2022.

This harmonization will definitely result in implementation of the unified rules on the territory of the member states of The EAEU. The Eurasian Economic Commission has already reviewed and agreed a number of drafts of pharmaceutical and medical device regulations including the Good Pharmacovigilance Practice, the Requirements for Patients Information Leaflets, Guidelines for Conducting Joint Pharmaceutical Inspections, the Rules on Materiovigilance, Quality and Efficacy of Medical Devices, and certain others. However, decisions to adopt these regulations have not yet been signed.

22.2 Regulatory Bodies

The regulatory bodies governing the healthcare system and pharmaceutical market of the Russian Federation are the Ministry of Healthcare (the “MOH”), the Ministry of Industry and Trade (the “MIT”) and the Federal Service for Surveillance in Healthcare (the “Federal Service”).

At this point the Russian GxP inspectorate has only been authorized to inspect foreign manufacturing sites for compliance with Russian GMP requirements. As a result, the creation of the inspectorate has not yet caused a redistribution of authorities among the state bodies.
The MOH is responsible for drawing up state policy and regulation in healthcare, circulation of medicines for human use, sanitary and epidemiological welfare and in numerous other areas. The MOH submits drafts of federal laws and acts of the President and of the Government on healthcare to the Government. The MOH also adopts a significant number of important executive regulations on circulation of medicines required by laws.

The MOH, among other things, also:

- Adopts rules for development of general pharmacopeial monographs, and publishes the state pharmacopoeia;
- Registers medicinal preparations for human use;
- Issues permits for the conduct of clinical trials;
- Issues permits for importation of a specific lot of unregistered medicines for their clinical trials, their expert examination for the purposes of state registration, and for rendering medical aid to a patient if he or she has extremely serious indications;
- Registers maximum manufacturers’ prices of medicinal preparations included into the list of essential and most important medicinal preparations, also known as the essential drug list (ED List, or EDL);
- Attests authorized persons of medicine manufacturers;
- Adopts rules on scientific consulting services on, inter alia, clinical trials and registration of medicinal preparations.

The MIT, among other things:

- Plays an important role in regulation of declaration of conformity and certification of medicinal preparations and medical devices;
Grants licenses for the manufacture of medicines;

Keeps a register of licenses granted;

Issues reports on the conformity of the medicines’ manufacturers to the Good Manufacturing Practice and keeps a register of such reports.

The Federal Service, among other things:

- Exercises control over the circulation of medical devices;
- Exercises control over the circulation of medicines;
- Exercises control over the quality of medicines;
- Monitors the assortment and prices of EDL medicinal preparations;
- Monitors the safety of medicinal preparations;
- Grants licenses for pharmaceutical activities;
- Keeps a register of licenses granted;
- Exercises control over the quality and safety of medical activity.

22.3 Clinical Trials of Medicinal Preparations and Clinical Studies of Medical Devices

The Law on Circulation of Medicines, similarly to its predecessor, contains a broad definition of clinical trials. It defines clinical trials as a study of the diagnostic, therapeutic, prophylactic, and pharmacological properties of a medicinal preparation in the process of its administration to humans and animals, including the study of the processes of its absorption, distribution, modification, and excretion, using scientific methods for the purposes of obtaining (i) evidence on the safety, quality, and efficacy of the medicinal preparation; (ii) data
on adverse reactions of humans and animals; and (iii) data on the effects of its interaction with other medicinal preparations and/or food products/ animal feed.

According to the Rules of Clinical Practice in the Russian Federation, adopted by Order of the Russian Ministry of Healthcare No. 266 dated 19 June 2003, a clinical trial is a study of the clinical, pharmacological and pharmacodynamic effects of the studied medicine on humans, including processes of absorption, distribution, modification and excretion, for the purposes of obtaining, through scientific methods of assessment, evidence of the efficacy and safety of medicines, and data on anticipated side effects and on the effects of interaction with other medicines.

Article 38 of the Law on Circulation of Medicines introduces the following possible objectives of a clinical trial:

- Ascertaining the safety of medicinal preparations on, and/or their tolerability by, healthy volunteers (not allowed on Russian territory for medicinal preparations manufactured outside Russia);

- The selection of optimal dosages of medicinal preparations, (ii) treatment courses for patients with a specific ailment, and (iii) selection of the optimal dosages and vaccination schemes for immunobiological preparations for healthy volunteers;

- Ascertaining (i) the safety and effectiveness of medicinal preparations for patients with a specific ailment, and (ii) the prophylactic efficiency of immunobiological preparations on healthy volunteers; or

- Studying the possibility of widening the indications for medical use of registered medicinal preparations, and identifying unknown side effects.

The amended Law on Circulation of Medicines separates the regulation of state registration of medicinal preparations and their
clinical trials. These regulatory processes were partially merged in the previous version of the Law on Circulation of Medicines. This increased the availability of certain types of clinical trials for unregistered medicinal preparations as it is no longer necessary to initiate the procedure for state registration of the relevant medicinal preparation or to organize its clinical trial as an international multicenter program in order to organize a clinical trial of an unregistered medicinal preparation in Russia.

The Law on Circulation of Medicines also lists bioequivalence and therapeutic equivalence studies as types of clinical studies of medicinal preparations.

Besides the two documents already mentioned governing clinical trials in Russia, the following two documents are also relevant to this process: Industry Standard OST 42-511-99 — Good Clinical Practice, adopted by the Russian Ministry of Healthcare on 29 December 1998, and National Standard of the Russian Federation GOST R 52379-2005 — Good Clinical Practice, adopted by Order of the Federal Agency on Technical Regulation and Metrology No. 232-st, dated 27 September 2005; both documents are derived from Good Clinical Practice (GCP) of the International Conference on Harmonization (ICH), the latter document being a direct translation.

A permit from the MOH is required to perform clinical trials. This permit is obtained by filing an application with the MOH together with the necessary documents. The MOH then orders the conduct of two expert examinations of the relevant clinical trial documents; an expert examination of the documents for obtaining a permit for performance of a clinical trial of a medicinal preparation concentrating on the scientific side of the trial in question, on the results of the preceding pre-clinical trial(s) of the relevant medicine and, if any, clinical trials of this medicinal preparation, and an ethical expert examination (concentrating on the ethical side of the trial in question with the aim of protecting the health and life of patients). These two expert examinations are performed respectively by a state institution for expert examination of medicines (employing attested
experts who perform expert examinations as part of their employment duties) and by the ethics council (composed of representatives of medical and scientific organizations, educational institutions of higher professional education as well as representatives of civic and religious organizations and the mass media). No other filings are necessary to obtain the permit and no direct communication between the applicant and the expert bodies is allowed.

Currently clinical studies of medical devices in Russia are regulated specifically in connection with the procedure for state registration of medical devices by Government Decree No. 1416 “On Approval of the Rules for Registration of Medical Devices”, dated 28 December 2012 (the “Rules for Registration of Medical Devices”). Therefore, the process of obtaining a permit to conduct clinical studies of medical devices will be described in the next chapter.

22.4 Registration of Medicinal Preparations and Medical Devices

Registration of medicinal preparations is regulated by the Law on Circulation of Medicines (Chapter 6).

Medicinal preparations can be manufactured, stored, transported, imported, exported, advertised, transferred, used, sold and destroyed on the territory of the Russian Federation only if they are registered with the MOH. More specifically, the following medicinal preparations (both Russian and foreign) are subject to state registration:

1. All medicinal preparations entering the Russian market for the first time;

2. Medicinal preparations registered earlier, but manufactured in different medicinal forms (in accordance with the list of names of medicinal forms), in new dosages provided the clinical significance and efficacy is proven; and
3. New combinations of medicinal preparations registered earlier.

The terminology of the amended Law on Circulation of Medicines is substantially different from its prior version. First of all, the term “original” medicinal preparation has been replaced with the term “reference” medicinal preparation. A reference medicinal preparation is a medicinal preparation that is registered in Russia for the first time, its quality, effectiveness and safety is proven by pre-clinical and clinical trials results, and which is used to ascertain bioequivalence or therapeutic equivalence, quality, effectiveness and safety of reproduced or biosimilar medicinal preparations.

Reference medicinal preparations are always registered using the results of their own clinical trials.

Reproduced medicinal preparations, i.e., generics, are medicinal preparations that have the same qualitative and quantitative composition of active substances in the same medicinal form as a reference medicinal preparation, the bioequivalence or therapeutic equivalence of which to the reference medicinal preparation is confirmed by the corresponding studies.

Secondly, the amended Law on Circulation of Medicines now regulates new and long-awaited categories of medicinal preparations, namely biological (a collective reference to immunobiological, human/animal blood/blood plasma derivatives, biotech and gene therapy medicinal preparations), biosimilar and orphan medicinal preparations.

The main idea behind the “bio” area of regulation is to differentiate biological generics (biosimilars) from plain generics. This is done so that biosimilar medicinal preparations can not be registered on the basis of a bioequivalence study and clinical trials will be necessary.
Orphan medicinal preparations are defined as medicinal preparations designed only for diagnostics of orphan diseases or their treatment aimed at the development mechanism of the disease.

Lastly, the amended Law on Circulation of Medicines now incorporates the concept of the owner (holder) of a registration certificate, which entails various regulatory duties. In the context of biotech or orphan medicinal preparations, the owner (holder) of the registration certificate is obliged to provide samples to other companies willing to conduct clinical trials (including comparative clinical trials) using them.

The complete state registration procedure for a medicinal preparation should not take longer than 160 working days (excluding the time for sending requests to the applicants if inaccurate information is discovered in the application or dossier and receiving the relevant responses to them) and is initiated through submission of an application with the necessary set of documents to the MOH.

The Law on Circulation of Medicines describes in great detail the set of documents and information to be submitted together with the application for the state registration of a medicinal preparation. This set of documents and information is termed a “common technical document”. Certain modifications to the requirements of this Russian CTD may be set for specific types of medicinal preparations.

The default rule for registration of medicinal preparations in Russia is that registration of a medicinal preparation new to the Russian market requires submission of the results of a clinical trial at least partially conducted in Russia. There are three exceptions to this general rule. All these exceptions are very different.

First of all, orphan medicinal preparations may be registered on the basis of the results of clinical trials conducted abroad.

Secondly, certain reproduced medicinal preparations may be registered without conducting any clinical trials, even in the form of
bioequivalence trials. These reproduced medicinal preparations include:

- water solutions for parenteral administration (subcutaneous, intramuscular, intravenous, intraocular, intracavitary, intraarticular, intracoronar);
- solutions for oral administration;
- powders or lyophilizates for preparation of solutions;
- gases;
- ear or eye medicinal preparations in the form of water solutions;
- water solutions for topical administration;
- water solutions used for inhalation with the use of nebulizers or as nasal sprays, administered with the use of similar devices.

These medicinal preparations, however, should have exactly the same composition as the relevant reference medicinal preparations (including composition of excipients). If the composition of excipients differs, the applicant should prove that excipients used in the reproduced medicinal preparation do not affect its safety and/or efficacy.

The last exception to the requirement for Russian clinical trials applies to medicinal preparations that have been allowed for medical use in Russia for more than 20 years.

According to the Law on Circulation of Medicines, the application for state registration of a medicinal preparation may be submitted to the MOH either by the company that developed the relevant medicinal preparation (the company owning the rights to the results of its
preclinical and clinical trials and to its manufacturing technology) or its representative (another legal entity).

Within 10 working days after the full application file is submitted, the MOH orders the following expert examinations to be conducted:

- an expert examinations of documents to ascertain whether the relevant medicinal preparation may be treated as an orphan medicinal preparation (if the applicant applied for orphan medicinal preparation status);

- an expert examination of the suggested methods of quality control of a medicine, and of the quality of the supplied samples of this medicine made with the use of these methods (shorter name — expert examination of the quality of the medicine) and an expert examination of the ratio between the expected benefit to the possible risks connected with use of the medicinal preparation (or the same expert examinations to be conducted within the expedited expert examination procedure).

The first expert examination should be conducted by an expert body within 30 working days. If its results are positive and medicinal preparation is recognized as orphan in Russia then the other two expert examinations are ordered to be conducted.

The expert examination of the quality of the medicine and the expert examination of the ratio between the expected benefit to the possible risks connected with use of the medicinal preparation should be conducted within 110 working days. Positive conclusions in both these expert examinations lead to registration of the medicinal preparation.

It is mentioned above that these expert examinations have expedited versions, which do not have different contents, but have the timing shortened to 80 working days.
Expedited expert examinations may be applied to the following medicinal preparations:

- orphan medicinal preparations;
- the first three reproduced medicinal preparations;
- medicinal preparations to be used exclusively for the treatment of minors.

Expedited expert examinations may not be applied to the following medicinal preparations:

- biosimilars;
- reference medicinal preparations (except for orphan medicinal preparations);
- reproduced medicinal preparations (except for the first three reproduced medicinal preparations and medicinal preparations to be used exclusively for the treatment of minors);
- new combinations of medicinal preparations registered earlier;
- medicinal preparations registered earlier, but manufactured in different medicinal forms (in accordance with the list of names of medicinal forms) and in new dosages.

It is important to note that there is no correlation between qualification for expedited expert examinations and the exception to the requirement for clinical trial results for registration of a medicinal preparation. Some medicinal preparations may qualify for both, while others for only one of these preferential regimes.

The amended Law on Circulation of Medicines limits cases in which pre-clinical and clinical trial data will be protected. Now only use for commercial purposes of pre-clinical and clinical data submitted by another applicant for the state registration of medicinal preparations.
will be prohibited for 6 years after the date of state registration of the reference (original) medicinal preparation. State registration of a generic medicinal preparation may now be initiated 4 years (3 years for biosimilars) after registration of the reference medicinal preparation. This is aimed at allowing generic medicines to appear on the Russian market immediately after the six-year data exclusivity period expires.

The amended Law on Circulation of Medicines re-establishes a grace period for medicinal preparations that recently had their registration dossier changed and allows circulation of medicinal preparations manufactured in accordance with the “old” registration dossier within 180 days after a decision of the registration authority to amend the registration dossier up until the expiration of their shelf life.

Registration of medical devices is performed by the Federal Service and is regulated by the Rules for Registration of Medical Devices. All medical devices circulated on the territory of the Russian Federation are subject to state registration except for medical devices produced under a patient’s individual order exclusively for his/her own use and medical devices intended to be used on the territory of an international medical cluster.

Currently registration of any medical device involves the performance of clinical studies. Clinical studies are performed in medical organizations approved for the conduct of clinical studies by the Federal Service, a list of which is published on the official web site of the Federal Service.

In accordance with the Rules for Registration of Medical Devices, the application for state registration of a medical device may be submitted to the Federal Service either by the company that developed (the developer) or manufactured (the manufacturer) the relevant medical device or by the authorized representative of the manufacturer. The authorized representative of the manufacturer is a legal entity, registered on the territory of the Russian Federation, authorized by the manufacturer of the medical device to represent its interests with
respect to circulation of the medical device on the territory of the Russian Federation, including with respect to issues of evaluation of conformity and state registration, and in the name of which the registration certificate of the medical device may be issued.

The Rules for Registration of Medical Devices do not, however, expressly require the registration certificate to be issued in the name of authorized representative of the manufacturer or otherwise only in the name of a Russian legal entity. Thus, the registration certificate can still be issued in the name of a foreign legal entity.

The complete state registration procedure for a medical device is initiated through submission of an application with the necessary set of documents to the Federal Service and should not take longer than 50 working days from the date the decision to commence state registration is adopted by the Federal Service (excluding the time for conducting clinical studies). Within 6 working days after submission of these documents the Federal Service orders two expert examinations: (i) an examination of the application for registration and supporting documentation in order to ascertain the possibility (impossibility) of conducting clinical studies (performed by a separate federal state institution); and (ii) an ethical expert examination of the possibility of conducting clinical studies of medical devices if such clinical studies involve human participation (performed by an ethics council in the sphere of circulation of medical devices). The first of these expert examinations should be conducted within 20 working days. The Rules for Registration of Medical Devices do not detail the length of an ethical expert examination. Upon receiving positive conclusions in these expert examinations, the Federal Service suspends the registration procedure while the clinical studies are performed.

After the clinical studies are completed the applicant needs to submit another application to the Federal Service to resume the registration procedure, together with the results of the clinical studies. After resuming the registration procedure, within 4 working days after receipt of the above listed documents, the Federal Service orders an
examination of the completeness and results of the performed technical tests, toxicological studies and clinical studies of the medical device. This expert examination should be conducted within 10 working days. A positive conclusion results in registration of the medical device by the Federal Service within 10 working days after receipt of these results.

22.5 Manufacturing

According to the Law on Licensing, the manufacture of medicines is a licensable type of activity. The licensing procedure is governed by the Regulation on Licensing the Manufacture of Medicines, approved by Government Resolution No. 686, dated 6 July 2012 (the “Regulation”). A license for manufacturing medicines is valid for an indefinite term.

As a general rule, only registered medicines may be manufactured in Russia. The manufacture of medicines is prohibited in the following cases:

1. The manufacture of medicines that are not included in the state register of medicines, except for medicines that are manufactured for the performance of clinical trials and for exportation;

2. The manufacture of falsified medicines;

3. If the manufacturer does not have a license for manufacturing medicines; and


A manufacturing legal entity is liable for noncompliance with the licensing requirements. The Regulation lists separate requirements to be satisfied by (i) license applicants in order to obtain licenses and (ii) licensees in order to maintain licenses, including complying with the
rules for manufacturing medicines established by Order of the MIT No. 916 On Approval of the Good Manufacturing Practice (GMP) dated 14 June 2013. The Law on Circulation of Medicines established that there should have been a gradual transition to the manufacture of medicines in accordance with these GMP standards in the period leading up to 31 December 2013 and compliance with this standard is now mandatory.

A manufacturing license is issued for certain types of activities listed in the Regulation. Whenever a licensee starts to perform new types of activities not indicated in its current license, it must apply for reissue of its license. The license must also be reissued if the address where manufacturing is conducted changes.

According to the Law on Licensing, manufacturing medical equipment is a licensable type of manufacturing activity. The licensing of medical equipment manufacturing will be abolished with the entry into force of technical regulations.

Currently the licensing procedure is formally governed by the Regulation on Licensing the Manufacture and Technical Maintenance (Except for Internal Needs) of Medical Equipment, approved by Resolution of the Russian Government No. 469, dated 3 June 2013.

In certain cases a license for manufacturing medical equipment alone is not sufficient and other licenses may be additionally required in order to lawfully manufacture certain types of medical equipment. For example, a license for activities involving sources of ionizing radiation would also be required if X-ray equipment is being manufactured.
22.6 Importation

In accordance with the Law on Circulation of Medicines, importation of medicines may only be performed by:

1. Manufacturers of medicines for their own manufacturing purposes;

2. Foreign developers of medicines or foreign manufacturers of medicines, or other legal entities as their representatives for the performance of clinical trials, state registration of medicinal preparations, inclusion of a pharmaceutical substance into the state register of medicines, and quality control of medicines subject to the permission of the Federal Service;

3. Organizations carrying out wholesale of medicines;

4. Scientific-research institutions, educational institutions of higher professional education or manufacturers: (i) for development of medicines, (ii) for trials of medicines, (iii) for control of medicines’ safety, quality and effectiveness subject to the permission of the Federal Service;

5. Medical organizations and other organizations mentioned in items 1–4 of this list for the purposes of rendering medical assistance to a specific patient if he or she has extremely serious indications, subject to the permission of the Federal Service.

Importation of medicines into the Russian Federation is governed by the Rules of Importation of Medicines Intended for Medical Use, adopted by Resolution of the Russian Government No. 771, dated 29 September 2010. In addition, since Russia is a member of the EAEU, decisions of the EuroAsian Economic Commission are binding on all members of the EAEU. In accordance with Decision No. 134 of the Board of the EuroAsian Economic Commission of 16 August 2012, importation licenses for properly registered medicinal preparations are
effectively abolished on the territory of the Customs Union. This marks a significant change in the way the medicines enter the territory of the Russian Federation. However, this measure is only aimed at reducing the amount of paperwork done by the relevant authorities and will not affect the mechanisms for control of imported medicinal preparations. This control will be performed directly at the stage of customs procedures in relation to these medicinal preparations.

Imported medicines are released onto the Russian market only after, inter alia, their conformity to applicable Russian requirements is confirmed. In this regard it is important to note that mandatory certification of medicines was replaced several years ago with a declaration of their conformity. This change caused a significant reaction in the Russian pharmaceutical market since a procedure aimed at minimizing state involvement in the pharmaceutical market turned out to be quite burdensome for foreign pharmaceutical manufacturers. Since then, however, certain medicines have been switched back to certification.

Similarly, imported medical devices are released into the Russian market only after, inter alia, their conformity is confirmed.

22.7 Wholesale

Pursuant to the Law on Licensing, pharmaceutical activity (including wholesale, retail sale and preparation of medicines) is a licensable type of activity. The licensing procedure is governed by the Regulation on the Licensing of Pharmaceutical Activities, approved by Resolution of the Russian Government No. 1081, dated 22 December 2011, as amended. A license for the performance of pharmaceutical activity is valid for an indefinite term.

Wholesale of medicines is currently governed by the Rules for Wholesale of Medicines, approved by Order No. 1222n of the Russian Ministry of Healthcare, dated 28 December 2010. This document, however, is likely to be replaced with the Good Distribution Practices
due to the new regulation in the amended Law on Circulation of Medicines. However, this replacement has not happened yet.

Wholesalers of medicines may sell medicines or place them at the disposal of the following legal entities and persons:

1. Other organizations carrying out wholesale of medicines;
2. Manufacturers of medicines for manufacturing purposes;
3. Pharmacy organizations;
4. Scientific-research institutions for scientific research purposes;
5. Individual entrepreneurs having medical or pharmaceutical activities licenses; and
6. Medical organizations.

Only duly registered medicines can be sold on the territory of the Russian Federation. Russian law explicitly prohibits the sale of falsified, poor quality and counterfeit medicines. An accompanying document must be executed for each particular medicinal preparation, stipulating, inter alia, the medicine’s name (international nonproprietary name and trade name), expiration date, information on the manufacturer, supplier, buyer, etc.

Administrative sanctions are established in Russia for breach of the rules on wholesale of medicines and sale of falsified, counterfeit or bad quality medicines (a separate offence is established if the sale of falsified, counterfeit or bad quality medicines results in harm to health or creates the threat of such harm).

The wholesale of medical devices does not require a license in Russia, unless the medical device in question is of any special type, e.g., an X-ray medical device. In the latter case wholesale of the medical devices
will require a license for activities involving sources of ionizing radiation.

22.8 Retail Sale

Retail sale of medicines is regulated by the Procedure for the Sale of Medicines, approved by Order of the MOH No. 785, dated 14 December 2005. This document, however, is likely to be replaced with the Good Pharmacy Practices due to the new regulation in the amended Law on Circulation of Medicines. However, this replacement has not happened yet.

Retail sale of medicines is exercised by pharmacy organizations, individual entrepreneurs having a pharmaceutical activities license, and medical organizations and their separate subdivisions located in rural settlements where there are no pharmacy organizations. Pharmacy organizations include pharmacies (selling ready-to-use medicinal preparations, production pharmacies, and production pharmacies having a right to produce aseptic medicinal preparations), pharmacy stations and pharmacy kiosks.

Prior to 2011 there existed a list of over-the-counter medicines and all other medicines, by default, had the status of prescription medicines. That list was abolished by Order of the MOH No. 1000an, dated 26 August 2011. Now sellers should dispense medicines exclusively in accordance with the instructions on their use.

Pharmacy institutions and individual entrepreneurs having a pharmaceutical activities license need to comply with a requirement for the minimum assortment of medicinal preparations necessary for rendering medical aid. The current minimum assortment of medicinal preparations is established by Government Resolution No. 2782-r dated 30 December 2014. It will be replaced starting from 1 March 2016 with a new assortment adopted by Government Resolution No. 2724-r dated 26 December 2015.
Similar to wholesale activity, retail sale of medicines is subject to licensing and only registered medicines can be sold in the Russian Federation.

Administrative sanctions are established in Russia for breach of the rules on retail sale of medicines and as in the case of wholesale of falsified, counterfeit or bad quality medicines, a separate offence is established if sale of falsified, counterfeit or bad quality medicines results in harm to health or creates the threat of such harm.

Retail sale of medical devices does not require a license in Russia, unless, as in the case with wholesale, the medical device in question is of any special type.

22.9 Price Regulation

The basis for the system of state regulation of the prices of medicines and its most general rules are set forth in the Law on Circulation of Medicines. The amended Law on Circulation of Medicines has more general and brief provisions on this issue compared to its previous version. Detailed regulations in this area have been adopted by the Russian Government, which now has more time for rule-making.

Under the Law on Circulation of Medicines and Government Resolution No. 865 On the State Regulation of Prices of Medicinal Preparations Included in the List of Essential and Most Important Medicinal Preparations, dated 29 October 2010 (“Resolution 865”), the price of medicinal preparations included in the EDL is controlled by the state, and is subject to state registration and mark-up regulation. Price control of EDL medicines is an important tool used in the organization of the healthcare system, ensuring that essential and most important medicines are accessible for all citizens. By law, revision of the EDL should be an annual process. The currently effective ED List is established by Government Resolution No. 2782-r, dated 30 December 2014. This list will be replaced starting from 1 March 2016 with a new list adopted by Government Resolution No. 2724-r, dated 26 December 2015.
According to the Law on Circulation of Medicines, the state regulation of prices of medicines included in the ED List is effected through the following measures:

- State registration of the maximum manufacturer’s prices of medicinal preparations (done at the federal level); and
- Establishing maximum wholesale and retail trade margins applied to the prices of medicinal preparations (done at the regional level).

On the basis of the application of the manufacturer of medicines included in the ED List submitted before 1 October of each following year, the maximum registered manufacturer prices of medicinal preparations can be re-registered once in a calendar year.

The calculation of the maximum manufacturer price of medicinal preparations is performed in accordance with the Calculation Methodology approved by Government Resolution No. 979, dated 15 September 2015.

Under the Law on Circulation of Medicines, Resolution No. 865 and Resolution of the Russian Government No. 239 “On Measures for Improvement of the State Regulation of Prices (Tariffs),” dated March 7, 1995, as amended (“Resolution No. 239”), the maximum wholesale and retail trade margins for medicines included in the ED List are established by regional governmental authorities.

Prices for other medicines (i.e., not included in the EDL) and medical devices are currently not regulated in Russia.

**22.10 Interchangeability**

The amended Law on Circulation of Medicines now provides the definition of interchangeable medicinal preparations and parameters of interchangeability (most importantly — the same pharmaceutical substance, which should translate into the same INN).
The procedure for establishing interchangeability is defined by Government Resolution No. 1154, dated 28 October 2015 (“Resolution No. 1154”).

The interchangeability of new medicinal preparations is defined during the state registration of medicinal preparations.

The deadline for establishing interchangeability for medicinal preparations registered both before, on and after 1 July 2015 is 31 December 2017. Starting from 1 January 2018 information on interchangeability will be included in the state register of medicinal preparations.

Interchangeability is established on the basis of equivalent qualitative and quantitative criteria of pharmaceutical substances, equivalent dosage form, equivalent or similar auxiliary substances, identical mode of administration, absence of clinically significant differences discovered in the course of the biosimilarities evaluation and compliance of the manufacturer with Good Manufacturing Practice.

The rules on interchangeability and Resolution No. 1154 do not apply to reference, herbal and homeopathic medicinal preparations, as well as to the medicinal preparations that have been permitted for medical use in Russia for over 20 years and cannot be reviewed for bioequivalence.

The Fundamentals establish the definition of interchangeability of medical devices such that they may be considered interchangeable if they are comparable in terms of their functional purpose, quality and technical characteristics and may replace one another. The Fundamentals further require the state register of medical devices to contain information on their interchangeability. However, as far as we are aware, the practice of defining interchangeability of medical devices is yet to develop.
22.11 Technical Maintenance of Medical Equipment

Technical maintenance of medical equipment is a licensable type of activity according to the Law on Licensing. The licensing procedure is governed by the Regulation on Licensing the Manufacture and Technical Maintenance (Except for Internal Needs) of Medical Equipment, approved by Resolution of the Russian Government No. 469, dated 3 June 2013. A license for the maintenance of medical equipment is valid for an indefinite term.

It should again be noted that in certain cases (similar to the licensing of manufacturing of medical equipment) a license for technical maintenance of medical equipment alone is not sufficient and other licenses may be additionally required in order to lawfully conduct technical maintenance of certain types of medical equipment (e.g., a license for activities involving sources of ionizing radiation is necessary when X-ray equipment is being serviced).

22.12 Government-run Programs for Medicinal Supply

The most important among government-run programs related to medicinal supply is the program for additional medicinal supplies for specific categories of citizens, lately referred to as the program for supply of essential medicines (the so-called DLO program or ONLS program (Russian abbreviations)) under which certain categories of citizens (social security beneficiaries) receive certain medicines free of charge. This program was established in 2004 (the first year of operation was 2005) through the introduction of amendments to the Social Care Law. The last quarter of 2007 was marked by significant reform of the ONLS program.

The reform of the ONLS program abolished price regulation in this sphere, transferred the program to the regional level, and subjected it to the usual government procurement rules so that purchases of medicines within the ONLS program are organized as auctions on the regional level.
However, part of the ONLS program remains at the federal level (but no longer bears this name) and is set up to supply expensive medicines for treatment of certain diseases (haemophilia, mucoviscidosis, hypophyseal nanism, Gaucher’s disease, malignant neoplasms in lymphoid, haematogenic tissues and other related tissues, disseminated sclerosis, and after transplantations). Expensive medicines are purchased through auctions by the MOH. The current list of such medicines was established by Government Resolution No. 2782-r, dated 30 December 2014. This list will be replaced starting from 1 March 2016 with a new list adopted by Government Resolution No. 2724-r, dated 26 December 2015.

Purchases of medicines within both programs, as well as any other purchases of medicines for state or municipal needs, are carried out in accordance with the new Federal Law No. 44-FZ On the Contractual System in the Supply of Goods, Performance of Works, and Rendering of Services for State and Municipal Needs, dated 5 April 2013, as amended.

In December 2015 the Russian Government adopted Government Resolution No. 1289 On Restrictions and Conditions on the Access of Medicinal Preparations Originating from Foreign Countries and Included into the List of Vital and Essential Medicines for the Purposes of Procurement for State and Municipal Needs (the “Resolution No. 1289”). Resolution No. 1289 is a part of the anti-crisis plan, developed by the Government earlier that aims to develop local manufacturing of medicines.

Resolution No. 1289 applies only to medicinal preparations included in the ED List. In a tender to conclude a single contract (single lot) to purchase a medicinal preparation included in the ED List, a state or municipal purchaser must reject any bid offering a medicinal preparation of foreign origin (or several medicinal preparations, one of which is of foreign origin), if there are two or more other bids which:

- offer one or more medicinal preparations, the country of origin of which is in the EAEU; and
• do not offer one and the same type of medicinal preparation from one manufacturer or manufacturers from the same group of companies (as defined in accordance with the antimonopoly legislation).

According to Resolution No. 1289, the country of origin of a medicinal preparation is evidenced by a certificate of origin of goods issued in accordance with the form and criteria for determining the country of origin provided for in the Agreement on the Rules of Determination of the Country of Origin in the Commonwealth of Independent States, dated 20 November 2009 (the “Customs Rules”).

Before that, in February 2015 the Russian Government adopted a similar Government Resolution No. 102 On Restricting the Access of Certain Types of Medical Devices Originating from Foreign Countries for the purposes of Procurement for State and Municipal Needs (the “Resolution No. 102”).

Resolution No. 102 contains a list of medical devices to which its provisions apply (the “List”). For medical devices included in the List a state purchaser must reject any bid offering a foreign medical device (other than those devices originating in Belarus, Kazakhstan or Armenia) if there are 2 or more other bids which:

• offer one or more medical devices included in the List, the country of origin of which is Russia, Belarus, Kazakhstan or Armenia; and

• do not offer one and the same type of medical device from one manufacturer.

The country of origin is also evidenced by the Customs Rules.
22.13 Promotion

The only type of promotional activity in the pharmaceuticals market that is currently specifically regulated by Russian law is “advertising”. Russian legislation contains few provisions that specifically regulate practices (other than simple advertising) aimed at the promotion or marketing of medicines. This means that, in order to determine the rules applicable to such things as seminars, hospitality, entertainment and similar activities, in most cases one has to refer to the generally applicable provisions of Russian law.

Advertising is defined in Article 3 of the Law on Advertising as “information spread by any means, in any form, and by any media, which is addressed to an indefinite circle of persons and aimed at drawing attention to the object advertised, at creating or maintaining interest in it, and at promoting it in the market”.

The Law on Advertising contains general restrictions on advertising that are as applicable to medicines and medical devices as they are to any other product. The general requirement is that the advertising should be fair and true. However, the Law on Advertising also contains specific provisions applicable to medicines and medical devices.

The Law on Advertising specifically requires that prescription medicinal preparations, medicines that contain narcotic or psychotropic substances approved for medical use, methods of prophylaxis, diagnostics, treatment and medical rehabilitation, medical devices that require special training for use can only be advertised in specialized printed publications intended for medical and pharmaceutical professionals, and at medical or pharmaceutical events.

Furthermore, the Law on Advertising requires that the advertisement of medicinal preparations, medical services, including methods of prophylaxis, diagnostics, treatment and medical rehabilitation, and medical devices must be accompanied by a warning regarding
contraindications against their use and application, the necessity to read the instructions on their use, or the necessity to consult a specialist. Such warning should last for at least three seconds in advertisements on radio programs; at least five seconds on television, film and video advertisements (not less than 7 percent of the frame area should be allocated to this warning); and not less than 5 percent of the area/volume in advertisements disseminated by other methods. This requirement, however, does not apply to advertisements disseminated at medical or pharmaceutical events and contained in specialized printed publications for medical and pharmaceutical professionals, nor to other advertisements where the recipients are solely medical and pharmaceutical professionals.

The Law on Advertising further introduces a group of restrictions that apply to the advertising of medicines. Thus, the advertising of medicines should not:

1. Be addressed to minors;

2. Contain references to specific cases of recovery from disease or improvement of health as a result of the advertised object being used (except in advertising exclusively for medical and pharmaceutical professionals);

3. Contain expressions of gratitude from individuals in connection with the use of the advertised object (except in advertising exclusively for medical and pharmaceutical professionals);

4. Create an impression of advantages of the advertised object by reference to the fact that the trials required for its state registration have been conducted;

5. Contain statements or assumptions that consumers have certain diseases or impairments of health;
6. Facilitate the impression that a healthy person needs to use the advertised object (this prohibition does not apply to medicines used for prevention of diseases);

7. Create an impression that one does not need to consult a physician;

8. Guarantee the positive effect of the advertised object, its safety, effectiveness and absence of side effects;

9. Represent the advertised object as being a dietary supplement or other product that is not a medicine;

10. Contain statements that the safety and/or effectiveness of the advertised object are guaranteed by its natural origin.

The advertising of medical services on induced abortion is prohibited. The restrictions in items 2 through 5 above are also applicable to the advertising of medical services, including methods of diagnosis, prophylaxis, treatment and medical rehabilitation; and the restrictions in items 1 through 8 above apply equally to the advertising of medical devices.

The Law on Advertising contains an important general prohibition against using images of medical and pharmaceutical professionals in any advertisements, except for advertisements for medical services, personal care products, and in advertising exclusively for medical and pharmaceutical professionals.

Further, by virtue of the Fundamentals, which came into force in the relevant part on 1 January 2012 (namely, Article 74) the interaction of pharmaceutical and medical devices companies with Russian medical and pharmaceutical professionals is substantially restricted. Although these rules are not specifically targeted at restricting marketing activities, they inevitably will significantly affect them. It is also important to note that these rules are not aimed at restricting lawful
interaction of pharmaceutical and medical devices companies with Russian healthcare institutions.

Most importantly, the Fundamentals prohibit medical and pharmaceutical professionals from:

- accepting visits of representatives of companies except for cases related to performance of clinical trials of medicinal preparations or clinical studies of medical devices, or participation of medical workers in meetings or other events related to their professional development or providing information on the safety of medicinal preparations and medical devices (in accordance with the procedure established by the management of a medical organization),

- accepting gifts or money, including payments for entertainment, vacations, travel costs, from pharmaceutical and medical devices companies (except for remuneration under agreements on clinical trials of medicinal preparations or clinical studies of medical devices, or for teaching and(or) scientific activities),

- participating in entertainment events held at the expense of companies or representatives of companies,

- accepting samples of medicinal preparations and medical devices for further distribution to patients (except in the context of clinical trials).

The Law on Circulation of Medicines has been subsequently amended to include an article on interaction with medical and pharmaceutical professionals largely duplicating Article 74 of the Fundamentals. Additionally, the following changes have been introduced into the Law on Circulation of Medicines:

- the Law on Circulation of Medicines now lists the requirements that pharmaceutical companies (their
representatives) must satisfy when organizing and/or financing scientific and other events aimed at the professional development of medical professionals or the provision of pharmacovigilance information;

- the Law on Circulation of Medicines prohibits hindering the participation of other companies that manufacture or distribute medicines with a similar pharmacological mechanism to that of medicines manufactured or distributed by the company organizing or financing the relevant event;

- companies (their representatives) must also make information on the event (its date, place and time, agenda, plan and participants) available by placing it on its official webpage not later than two months prior to the event. They are also required to pass the above information to the Federal Service, which should then place it on its official website.

A separate administrative offence has been established for failure to provide the authorized state body with information if required to do so by healthcare legislation. Even though it is not certain yet, this rule is likely to apply to pharmaceutical companies for failure to inform the Federal Service about events they organize and/or finance.

Surprisingly, the long-awaited amendments to the Code of Administrative Offences of the Russian Federation for violation of Article 74 of the Fundamentals (governing interactions with medical and pharmaceutical professionals) have not yet been introduced.