

## **19. PHARMACEUTICALS AND HEALTHCARE INDUSTRY**

### **19.1 Legal Framework**

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 basis of the Russian healthcare system is laid out in *Fundamentals of the Legislation of the Russian Federation on Citizens' Health Protection* No. 5487-1, dated July 22, 1993 (the "Fundamentals"). Federal Law No. 178-FZ *On State Social Care* dated July 17, 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. 86-FZ *On Medicines*, dated June 22, 1998, (the "Law on Medicines"). Up until today no specific law was passed, which would separately regulate medical devices and medical equipment, even though an attempt to pass such a law was made.

Other laws that are also important for the pharmaceuticals and healthcare sector include Federal Law No. 184-FZ *On Technical Regulation*, dated December 27, 2002 governing technical regulation, namely declaration of the conformity of medicines and certification of medical devices and medical equipment (the "Law on Technical Regulation"), Federal Law No. 38-FZ *On Advertising*, dated March 13, 2006 (the "Law on Advertising") governing advertising of medicines, medical equipment, medical products and medical services, Federal Law No. 128-FZ *On Licensing of Certain Types of Activities*, dated August 8, 2001 (the "Law on Licensing") governing licensing in the Russian Federation.

### **19.2 Regulatory Bodies**

The regulatory bodies governing the healthcare system and pharmaceutical market of the Russian Federation are the Ministry of Healthcare and Social Development (the "MOH") and the Federal Service for Surveillance in Healthcare and Social Development (the "Federal Service").

The MOH is responsible for drawing up state policy and regulation in the sphere of healthcare and social development. The MOH submits to the Government of the Russian Federation the drafts of federal constitutional laws, federal laws, acts of the

President and the Government in the sphere of healthcare, including on organization of medical assistance, related to pharmaceutical activity, quality, efficiency and safety of medicines.

The Federal Service grants licenses for manufacturing medicines, pharmaceutical activities (retail sale, wholesale of medicines and preparation of medicines), medical activities (medical works and services), manufacturing of prosthetic and orthopedic appliances, activities, related to circulation of narcotics and psychotropic substances, manufacturing of medical equipment and technical maintenance of medical equipment; keeps a register of licenses granted; exercises state control in the sphere of circulation of medicines; registers medicines and medical products; conducts accreditation and certification. Even though the Federal Service can not adopt legal rules itself (and due to this the most important documents initiated by the Federal Service are adopted by the MOH), documents issued by it in practice nonetheless should be taken into account by participants in the pharmaceutical market.

### **19.3 Clinical Trials of Medicines and Medical Tests of Medical Products**

Registration (and thus circulation) of any new medicine on the Russian market is preceded by clinical trials of this medicine in Russia. Sometimes clinical trials are also conducted after the relevant medicine is registered.

According to Article 37 of the Law on Medicines, the purpose of the clinical trials of medicines is to obtain, through scientific methods, the evaluation and proof of the effectiveness and safety of medicines, data on possible side effects of the use of medicines and the effects of their interaction with other medicines. 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, pharmacodynamic effects of the studied medicine in 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 the medicines, data on anticipated side effects of the medicines and on the effects of interaction with other medicines.

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 December 29, 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 September 27, 2005, both documents being the translations of ICH GCP with the latter being identical translation.

Each clinical trial may only be performed after its conduct is approved by the Ethics Committee of the Federal Service (operating in accordance with Order of the Federal Service No. 2314-Pr/07 dated August 17, 2007) and the Federal Service (given in accordance with the procedure established by Order of the Russian Ministry of Healthcare No. 103 dated March 24, 2000).

Registration of medical products also requires providing the Federal Service with the evidence of their quality, effectiveness and safety according to Administrative Regulation of the Federal Service *On Exercising the State Function of State Registration of Medical Products*, approved by Order No. 735 of the MOH, dated October 30, 2006. Such evidence is usually obtained in course of medical tests. State regulation of medical tests of medical products is less stringent compared to clinical trials of medicines.

## **19.4 Registration of Medicines**

Registration of medicines is regulated by the Law on Medicines (Article 19) and Administrative Regulation of the Federal Service *On Exercising the State Function of State Registration of Medicines*, approved by Order No. 736 of the MOH, dated October 30, 2006.

Medicines can be manufactured, sold and used on the territory of the Russian Federation only if they are registered by the Federal Service. The following medicines (both Russian and foreign) are subject to state registration:

- 1) new medicines;
- 2) new combinations of medicines registered earlier;
- 3) medicines registered earlier, but manufactured with different dosages or different excipients;
- 4) reproduced medicines (i.e., generic medicines).

According to the Law on Medicines the application for the state registration of medicines may be submitted to the Federal Service either by the company-developer of the relevant medicine (holder of the patent rights for the medicine and of copyright to the results of preclinical trials) or its representative. In practice however the Federal Service also accepts applications from owners of rights to the intellectual property

with respect to the dossiers of medicines and with respect to the results of their pre-clinical trials (in the case of generic medicines) and from manufacturers of the relevant medicines (in all cases assuming they are duly empowered by the developers of the medicines to perform registration).

Even though the registration is performed by the Federal Service the usual process for registration of medicines in Russia starts not at the Federal Service itself, but at its subordinate organization FGU NC ESMP (Federal State Institution Scientific Center for Expert Examination of Means of Medical Use), which performs expert examination of application dossiers which are then submitted to the Federal Service.

Registration of medical products is also performed by the Federal Service and is regulated by Administrative Regulation of the Federal Service *On Exercising the State Function of State Registration of Medical Products*, approved by Order No. 735 of the MOH, dated October 30, 2006.

Registration process differs depending on the class of the medical device. There are four classes of medical products (1, 2a, 2b, 3) which are differentiated depending on the amount of risk their application entails.

The application for registration must be filed either by the manufacturer of the relevant medical product or by its representative.

## **19.5 Manufacturing**

According to the Law on Licensing, manufacturing of medicines is a licensable type of activity. The licensing procedure is governed by the Regulation on Licensing the Manufacture of Medicines approved by Resolution of the Russian Government No. 415 dated July 6, 2006. A license for manufacturing medicines is valid for five years and then can be prolonged.

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

- 1) medicines have not undergone state registration in the Russian Federation with the exception of medicines intended for clinical trials;
- 2) the manufacturer does not have a license for manufacturing medicines;
- 3) manufacturing of medicines in breach of rules related to organization of the manufacturing of medicines and the control of their quality, approved by the MOH.

The legal entity - manufacturer of medicines - is liable for noncompliance with the rules for manufacturing medicines currently established in the National Standard of the Russian Federation Good Manufacturing Practice for Medicinal Products (GMP) GOST R 55249 - 2004 adopted by Decree of the Russian State Committee on Standardization and Metrology No. 160-st dated March 10, 2004.

Medical products in Russia are divided into two categories, medical equipment and products of a medical purpose. According to the Law on Licensing, manufacturing of medical equipment only is a licensable type of activity. The licensing procedure is governed by the Regulation on Licensing of Manufacturing of Medical Equipment approved by Resolution of the Russian Government No. 33 dated January 22, 2007. A license for manufacturing medical equipment is valid for five years and then can be prolonged.

It should be noted that in certain cases the license for manufacturing medical equipment alone will not be 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 will also be required when, inter alia, X-ray equipment is being manufactured.

## **19.6 Importation**

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

- 1) organizations manufacturing medicines for their own manufacturing purposes;
- 2) organizations carrying out wholesale of medicines;
- 3) scientific-research institutions and laboratories for development, studies and quality effectiveness and safety control, under the permission of the Federal Service;
- 4) foreign organizations-manufacturers and wholesalers of the medicines if such organizations have representative offices in Russia.

Importation of medicines into the Russian Federation is governed by the Procedure for Importation and Exportation of Medicines Intended for Medical Use adopted by Resolution of the Russian Government No. 438 dated July 16, 2005. This document establishes that importation of the medicines is performed on the basis of an importation license issued by the Russian Ministry of Economic Development and

Trade (the “MERT”) on the basis of a positive conclusion issued by the Federal Service. However, due to liquidation of the MERT in 2008 its functions of regulation of foreign trade activities were transferred to the Russian Ministry of Industry and Trade.

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 with declaration of their conformity. This change caused significant reaction in the Russian pharmaceutical market as the procedure aimed at minimizing state involvement in the pharmaceutical market turned out to be quite burdensome for foreign pharmaceutical manufacturers.

Importation of the medical products is not subject to the conditions and limitations applicable to medicines and is performed in the ordinary course of importation.

Imported medical products are released onto the Russian market only after, inter alia, they are duly certified. It should be noted that certification of all medical products in Russia is performed according to the rules for certification of electrical equipment established in Decree of the Russian State Committee on Standardization and Metrology No. 36 dated July 16, 1999.

## **19.7 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 Licensing of Pharmaceutical Activities approved by Resolution of the Russian Government No. 416 dated July 6, 2006. A license for performance of pharmaceutical activity is valid for five years and can be prolonged thereafter.

Wholesale of medicines is governed by the Rules for Wholesale of Medicines approved by Order No. 80 of the Russian Ministry of Healthcare dated March 15, 2002.

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) organizations manufacturing medicines for their own manufacturing purposes;
- 3) pharmaceutical institutions;
- 4) scientific-research institutions for research purposes;
- 5) individual entrepreneurs having medical activities licenses.

Only duly registered medicines can be sold on the territory of the Russian Federation. Russian law also explicitly prohibits the sale of medicines with an expired period of validity and counterfeit medicines.

Wholesalers should meet the requirements of state standards, sanitary, veterinary and fire-prevention rules, work safety, accident prevention and other regulatory requirements. Wholesalers should use proper premises, equipment and inventory which ensure the quality and safety of medicines during their storage and disposal and ensure compliance with wholesale procedures.

Wholesale of medical products is not a licensable activity in Russia.

## **19.8 Retail Sale**

Retail sale of medicines is regulated by the Rules for Sale of Medicines in Pharmaceutical Institutions, Fundamental Provisions (OST 91500.05.0007-2003), approved by Order No. 80 of the Russian Ministry of Healthcare dated March 4, 2003 and by Order on the Sale of Medicines approved by Order of the MOH No. 785 dated December 14, 2005.

Retail sale of medicines is exercised by pharmaceutical institutions, which include pharmacies, pharmacy kiosks, pharmacy stores and pharmacy stations. These types of pharmaceutical institutions differ in the scope of activities that they can perform, for example, prescription medicines may only be sold through pharmacies and pharmacy stations, while over-the-counter medicines may be also sold in pharmacy stores and pharmacy kiosks.

The MOH establishes a list of over-the-counter medicines. All other medicines have the status of prescription medicines. The current list of over-the-counter medicines is established in Order of the MOH No. 578 dated September 13, 2005.

Notably, pharmacy institutions need to comply with a requirement of minimum assortment of medicines. The current minimum assortment of medicines is established by Order of the MOH No. 312 On Minimum Assortment of Medicines dated April 29, 2005.

Similar to wholesale activity, retail sale of medicines is subject to licensing and only registered medicines can be sold in the Russian Federation.

Retail sale of medical products is not a licensable activity in Russia.

## 19.9 Price Regulation

Generally, according to the Law on Medicines, prices of medicines may be subject to state regulation. Further, according to Decree of the Russian Government No. 239 On Measures for Improvement of State Regulation of Prices (Tariffs) dated March 7, 1995, as amended, trade margins to the prices of medicines may be established by the executive bodies of the regions of the Russian Federation.

Pursuant to Russian Federation Government Resolution No. 782 *On State Control of Prices of Medicines* dated November 9, 2001 (“Resolution No. 782”), the price of medicines included in the list of vitally necessary and most important medicines (the essential drug list or the “ED List”) is controlled by the state and subject to mandatory state registration. Price control with respect to certain medicines is an important tool of the healthcare system ensuring that the most important medicines are accessible for all citizens. The price for other medicines (i.e., not included in the list of vitally necessary and most important medicines) is not regulated by the state and can, therefore, be freely established by the sellers. Currently the ED List is established by Government Ordinance No. 376-r dated March 29, 2007 while 24-th edition of the register of prices is published by Letter of the Federal Service No. 011-24/09 dated January 26, 2009.

According to Resolution No. 782, 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 medicines (done at the federal level), and
- establishing the maximum wholesale and retail trade margins applied to the prices of medicines (done at the regional level).

Under the Procedure for State Regulation of Prices of Vitally Necessary and Most Important Medicines introduced by Resolution No. 782 (hereinafter - the “Procedure”) the manufacturer’s price for medicines included in the ED List must be formally agreed and registered with the Federal Service. The internal procedures of the Federal Service with regard to price registration are governed by the Administrative Regulation of the Federal Service on Execution of the State Function of State Registration of Maximum Selling Price of Medicines adopted by Order of the MOH dated December 31, 2006 No. 907.

Under Resolution No. 782, the maximum wholesale and retail trade margins for medicines included into the ED List are established by the regional governmental authorities.

Since the wholesale/retail margins are defined on a regional level, it is not clear which region's margins are to be used for the purposes of inter-regional trade. According to the position of the Russian Ministry of Economics and the Ministry of Healthcare stated in their Letter No. MB-576/7-968, No. 2510/9695-99-32 dated September 6, 1999, where a wholesale distributor (*e.g.*, located in Moscow) sells medicines to a customer located in another region, the applicable margins should be defined under the rules of that other region.

## **19.10 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 of Technical Maintenance of Medical Equipment (Except when such Activity is Carried out to Satisfy the Own Needs of a Legal Entity or Private Entrepreneur) approved by Resolution of the Russian Government No. 32 dated January 22, 2007. A license for maintenance of medical equipment is valid for five years and then can be prolonged.

It should again be noted that in certain cases (similar to the licensing of manufacturing of medical equipment) the license for technical maintenance of medical equipment alone will not be 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, inter alia, X-ray equipment is being serviced).

## **19.11 Government-Run Programs for Medicinal Supply**

The most important among government-run programs related to medicinal supply is the program for additional medicinal supply of specific categories of citizens lately referred to as a program of supply of essential medicines (the so-called DLO program or ONLS program) 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 into 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 on the federal level (and no longer bears this name) and is set up for the purposes of supply of expensive medicines for treatment of certain nosologies (haemophilia, mucoviscidosis, hypophyseal nanism, Gaucher's disease, myeloleukemia, disseminated sclerosis and after transplantations). Expensive medicines are purchased through auctions by the MOH.

Purchases of medicines within both programs, as well any other purchases of medicines for state or municipal needs are carried out in accordance with Federal Law No. 94-FZ On placement of Orders for Supply of Goods, Performance of Works and rendering of Services for State and Municipal Needs dated July 21, 2005, as amended.

## **19.12 Promotion**

The only type of promotional activity in the pharmaceuticals market that is 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 practices 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 "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 products 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 products.

Under the Law on Advertising prescription medicines, as well as medicines that contain narcotic or psychotropic substances approved for medical use, treatment

methods, medical products and equipment that require special training for their use may only be advertised in specialized printed publications intended for medical and pharmaceutical professionals and at medical or pharmaceutical events.

The Law on Advertising contains a requirement that the advertisement of medicines, medical services and medical equipment 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. 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 and 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 the 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.

Please note that the restrictions in items 2 through 5 above are also applicable to the advertising of medical services, and the restrictions in items 1 through 6 above apply equally to the advertising of medical equipment.

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

## 20. TELECOMMUNICATIONS

### 20.1 Applicable Laws and Competent State Bodies

The general rules in the telecommunications sphere in the Russian Federation are established by the law “*On Communications*” dated 7 July 2003 (the “**Communications Law**”). The Communications Law governs communications activities in the Russian Federation and assigns certain policy and regulatory functions to various bodies. The Communications Law also establishes a separate procedure for licensing and certification in the sphere of telecommunications.

State regulations on the provision of services and other telecommunications activities are to be drafted by the President, the Government, and the Ministry of Information Technologies and Communications (the “**MITC**”) - the federal governmental authority for communications.

The MITC is the state body responsible for the preparation of draft federal laws, presidential decrees and government resolutions in the area of communications and information technology. The MITC is also entitled to issue its own regulations, such as setting out requirements for the use of numbering capacity, regulations on the use of radio frequencies, rules for providing communications services to subscribers, etc.

The other state agencies in the sphere of telecommunications are: the Federal Service for Supervision in the Sphere of Telecommunications, Information Technology and Mass Communications (“**Roskomnadzor**”), the Federal Agency for Information Technology (the “**FAIT**”), and Rossvyaz - the Federal Communications Agency (the “**FCA**”).