



## **Legal Issues in the Construction of a New Pharmaceuticals Factory in Russia**

By: The Pharmaceutical Industry Practice Group  
of Capital Legal Services,  
Moscow and St. Petersburg, Russia<sup>1</sup>

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This article summarizes the principal legal issues in construction of a new pharmaceuticals factory in Russia in 2011. These issues concern: (1) investment incentives Russian regions may offer; (2) investment incentives that may be obtained by participating in the Skolkovo project; (3) acquiring land use rights; (4) using of FIDIC construction contracts; (5) licenses required to operate a pharmaceuticals factory; and (6) permits required to operate a pharmaceuticals factory.

### **(1) Investment Incentives Russian Regions May Offer**

A pharmaceuticals manufacturer seriously considering constructing a new factory to produce pharmaceutical products in Russia may enter into negotiations with the government of the alternative Russian region to receive for the following investment incentives. Our firm has experience in such negotiations to obtain the best possible investment conditions and to see a project through from inception to fully-licensed production of goods.

#### **1.1 Inclusion in the Region's List of Priority Projects**

An investor may request that its potential project to construct a pharmaceuticals manufacturing facility be included in the list of priority investment projects of the particular regions under consideration.

#### **1.2 Reduction of Profit Tax**

An investor may request reduction of the rate of the portion of the corporate profit tax credited to the regional budget to 13.5% from 20%.

#### **1.3 Reduction of Property Tax**

An investor may request reduction of property tax to zero percent (0%), rather than 2.2 %.

#### **1.4 Reduction of Transportation Tax**

An investor may request reduction of the transportation tax to zero percent (0%), rather than 12.5%.

#### **1.5 Other Financial Incentives**

An investor may request the availability of (a) an investment tax credit, in an amount to be agreed; (b) state-financed credit, in an amount to be agreed; and (c) a state guarantee, in an amount and with terms to be agreed.

1.6 Advantageous Land Use Rights

An investor may request a choice between several possible locations in a particular region for construction of the proposed factory, with each location to be made available to the investor without the conducting of a public tender, or by means of a preliminary agreement about the location of the planned factory, including agreement for a designated permitted use of a site that will permit the planned factory to be constructed at a particular location.

1.7 Advantageous Land Lease Rates

An investor may seek a significant discount on the standard land lease rates.

1.8 Access to Infrastructure

An investor may request immediate access to all necessary electricity, gas and water utility infrastructure, and at minimal cost. For this purpose, the investor may give a preference to locations that have existing infrastructure.

1.9 Rapid Regulatory Approvals

An investor may request assurance that a region shall promptly provide all regulatory approvals and permits that may be required to realize the project promptly and without any unscheduled expenses. An investor may request that a duly authorized representative of the regional government be given responsibility and adequate authority to oversee and facilitate the delivery to the investor of all regulatory approvals that may become required. And, the investor may request that the regional government give assurances that it will assist the investor in all possible ways to resolve any organizational problems in implementing the project and neither conduct nor initiate any actions that might oblige the investor to make any additional financial payment or investment not agreed at the outset of the project.

1.10 Support for employees

An investor may request that a regional government give timely assistance to the investor in obtaining visas, permits and other documents necessary for foreign employees of the investor.

1.11 Guarantee of Best Investment Conditions Offered by the Region

An investor may request assurance that it shall receive every investment incentive that has been made available by the regional or city government to any foreign or Russian investor who has located a new factory, or reconstructed a factory in the region or city in recent years, and no better investment conditions shall be offered to any investor between the date of commitment to a project and a date 5 years following completion of the investor's proposed investment. If the investor learns of any investment benefits or conditions that have been offered to another investor in the region, the investor may obtain a right, retroactive to commencement of the project, to receive the same investment benefits or conditions. The investor may request access, to the maximum extent possible, to the operative documents showing the investment conditions given to other foreign investors in a region in recent years.

## **(2) Investment Incentives that may be Obtained by Participating in the Skolkovo Project**

Investment in a pharmaceuticals factory may also qualify for tax, customs, and other benefits by being a part of a project of the Russian government to stimulate investment into innovative technologies that is referred to as the "Skolkovo project." Medical technologies are a type of innovative technology that qualifies for inclusion in the Skolkovo project.<sup>2</sup>

The Skolkovo legislation does not require that research be conducted, or a new factory physically located in the Skolkovo area outside of Moscow. It is sufficient for a project to be accepted as part of the Skolkovo project regardless of where in Russia the project is physically located.

Some of the investment incentives offered to participants in the Skolkovo project include the following:<sup>3</sup> project participants do not pay value added tax ("VAT") on domestic purchases of goods and services, and may earn three hundred million rubles without payment of Russian corporate profits. There is an exemption from otherwise obligatory social and medical insurance taxes, and pension taxes are set at a lower rate than generally applicable, 14 percent rather than 26 percent of payroll starting in 2011. The Skolkovo managing company will be able to act as the customs broker for participant companies regarding equipment connected to Skolkovo. Project participants may reclaim import VAT and customs duties paid through the management company when goods are imported for a project that is included in the Skolkovo project. Project participants are exempt from the general rules governing employment of foreigners. Work permits will be issued by the managing company without restriction by government quotas for employment of foreign persons.

The main criteria for a project to qualify for inclusion in the Skolkovo project are not definitely determined as of today. But, according to members of Skolkovo management, the following criteria will be used: a minimum investments must be made of more than one million dollars; the investor must make a long-term commitment to its project; the project must be considered by Skolkovo management to be viable; the project must match the objectives of the Skolkovo project; the project must be innovative; and the project must require scientific and international cooperation.

## **(3) Acquiring Land Use Rights**

Factories in Russia may be built on land plots that are either leased or owned. Generally speaking, there are two categories of available land plots, state and municipal land, and privately owned land.

If land is leased, a lease signed for a term of longer than a year is subject to state registration. A lease of private land can be entered into without an auction. In contrast, a lease of state land may be entered into only in compliance with the procedure described in Article 30 of the Land Code of the Russian Federation (the "Land Code") which provides for (a) an allocation of a land plot for construction purposes without preliminary approval of facility location through an auction;<sup>4</sup> or (b) an allocation of a land plot for construction purposes with preliminary approval of facility location without an auction.<sup>5</sup>

Allocation of a land plot for construction purposes with preliminary approval of the facility's location may take place when a land plot, feasibility of investment project and basic construction parameters are not determined and require specification on an individual basis upon application by an investor. Land plots may be allocated for construction purposes with preliminary approval of facility location only on a leasehold basis.<sup>6</sup>

Russian land legislation stipulates the following cases when preliminary approval of facility location is not applied: (a) a land plot is formed but not vested in someone's possession;<sup>7</sup> (b) the location of a facility in urban and rural settlement is in accordance with town-planning documentation and regulations on land use and development;<sup>8</sup> and (c) other cases not related to construction of factories.

According to Clause 2 Article 30 of the Land Code, land plots may be allocated for construction purposes into ownership without preliminary approval of facility location only on the basis of a tender, with the exception of cases established in that article.

Russian land legislation provides a special procedure for acquisition of land plots under owned buildings. Legal entities possessing duly registered ownership title to buildings and structures on state-owned land plots or land plots owned by municipal authorities have an exclusive right to purchase or lease the land plots.<sup>9</sup>

As regards the choice whether to construct a factory on owned or leased land, it is not possible in all locations to purchase land, though a long-term lease for 25 or 49 years is generally available. Generally, the land tax that is payable for owned land is always several times less than the rent that would be payable to lease the land.

#### **(4) Use of FIDIC Contracts**

At present, there are no rules in Russia establishing standard forms of construction contracts. At the same time, there are standard forms of construction contracts developed by international organizations, in particular, standards forms of the Federation Internationale des Ingenieurs-Conseils (“FIDIC”), JCT (Joint Contracts Tribunal), ICE (Institution of Civil Engineers), NEC, IMechE, and a number of other European and US associations and organizations.

Construction contracts by FIDIC are most popular in Russia. Many foreign developers and construction contractors carry out their work under FIDIC contracts. The reason is that FIDIC contracts are used by international financial institutions, including the World Bank, European Bank for Reconstruction and Development, and Asian Development Bank. FIDIC contracts are highly appreciated by construction professionals for being clear and consistent in every respect, and for the structural compatibility of any contract within the FIDIC group with other FIDIC contracts. In addition, FIDIC contracts have successfully been used over a number of years in various countries with different legislation.

FIDIC has developed seven main contract forms: (1) Conditions of Contract for Construction for Building and Engineering Works designed by the Employer (“Red Book”); (2) Short Form of Contract (“Green Book”); (3) Client/Consultant Model Services Agreement (“White Book”); (4) Conditions of Contract for Design-Build and Turnkey (“Orange Book”); (5) Conditions of Contract for Plant & Design-Build for Electrical & Mech. Plant & For Building & Engineering Works Designed by the Contractor (“Yellow Book”); (6) Conditions of Contract for Design, Build and Operate Projects (“Gold Book”); and (7) Conditions of Contract for EPC Turnkey Projects (“Silver Book”). As a general rule, FIDIC contracts include the following clauses: (1) Contract Agreement; (2) Letter of Tender; (3) Letter of Acceptance; (4) Conditions of Contract; (5) Specification; (6) Drawings; (7) Schedules; (8) Dispute Adjudication Agreement.

When using standard FIDIC contracts in Russia, it is necessary to adjust them to be in line with Russian legislation. A number of standard FIDIC conditions contradict Russian law.

#### **(5) Licenses and Permits**

##### **5.1 Licenses to Manufacturing Drugs**

In order to manufacture drugs in a new facility in Russia, a specific license is required.<sup>10</sup> If the manufacturing process will involve production of new pharmaceutical forms, or new active ingredients, a company must obtain a new license for production of drugs.<sup>11</sup>

A license for the manufacture of drugs is issued by the Ministry of Industry and Trade (Minpromtorg), except for the manufacture of veterinary drugs, which is issued by the Federal Service for Veterinary and Phytosanitary Control.<sup>12</sup> Such licenses entitle their holder to manufacture drugs at one, several or all stages of the manufacturing process, and to store and sell the drugs produced.<sup>13</sup>

In order to obtain such a license, a company must file an application and the documents: (a) copies of documents confirming ownership of the premises and equipment for the manufacture of drugs or other legal grounds or documents confirming the legal grounds for using the buildings and equipment owned by another entity; (b) a list of pharmaceutical forms and/or active pharmaceutical ingredients which the applicant intends to produce; (c) a copy of a document confirming compliance of the premises and equipment for production of drugs with the sanitary rules and regulations; (d) copies of documents confirming professional qualification of employees responsible for production and marking of drugs; and (e) documents indicated in Clause 1 Article 9 of the Federal Law “On licensing certain types of activities.”<sup>14</sup> Notarized or original copies of documents should be submitted.<sup>15</sup> The licensing authority should decide whether a license will be issued within 45 days starting from receiving the application and documents.<sup>16</sup>

The holder of a license is obliged to: (a) arrange the manufacturing procedure in compliance with the rules for drug quality control; (b) have employees responsible for regulatory compliance who have specialized higher education and relevant employment experience of no less than five years; (c) meet requirements for price limitations for vital and essential drugs; and (d) meet other license requirements indicated in the regulation on licensing the production of drugs.<sup>17</sup>

## 5.2 License to Conduct a Pharmaceutical Activity

A license to conduct pharmaceutical activity entitles the holder to carry out the wholesale and retail sale of drugs, and their storage, transportation and distribution.<sup>18</sup> A license for conducting pharmaceutical activity is not required for a pharmaceutical manufacturing facility in the event the factory only produces and sells drugs and conducts no other activities in the pharmaceutical field. But, in the event a company desires its factory to participate in the wholesale and retail sale of drugs, it needs to obtain a license for conducting pharmaceutical activity.

Licenses for conducting pharmaceutical activity are issued by the Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor) and by regional executive authorities. The set of documents required for obtaining a license for conducting pharmaceutical activity includes: (a) copies of documents confirming the ownership of the premises and equipment used for conducting the pharmaceutical activity; (b) a copy of a report on a sanitary expert examination pertaining to compliance of the premises with sanitary rules and regulations; (c) a copy of a diploma of higher pharmaceutical education or secondary-level pharmaceutical education and advanced education of the company’s employees responsible for introducing the drugs to the market; and (d) documents indicated in Clause 1 Article 9 of the Federal Law “On licensing certain types of activities.”<sup>19</sup> Notarized or original copies of these documents should be submitted.<sup>20</sup>

## 5.3 Licenses for Specific Medical Products

The licenses discussed above concern the manufacture of drugs which do not contain narcotic or psychotropic substances. These licenses also do not cover medical devices. If manufacturing drugs with narcotic and psychotropic substances, additional licenses will be required. There are four types of such licenses depending on the category of narcotic or psychotropic substances used in a drug.<sup>21</sup> If manufacturing medical devices such as glucose meters, thermometers, inhalators, etc., a license will be needed for manufacturing such medical devices.<sup>22</sup>

#### 5.4 License if a Chemical Hazard

This license is required if a factory is recognized as a facility presenting a chemical hazard. This will occur if toxic or highly toxic substances or other substances dangerous for the environment are used, remade, formed, stored, transported or destroyed in the facility.<sup>23</sup> The chemical traits of substances recognized as toxic are defined in the Federal Law No.116-FZ “On industrial safety of hazardous manufacturing facilities” dated 21.07.1997 (the “Industrial Safety Law”).<sup>24</sup>

A license for operating an industrial facility with a chemical hazard is to be issued by the Regional Department of the Federal Service for Ecological, Technological and Nuclear Control. The main license requirements are determined by the Industrial Safety Law and mainly concern strict requirements for the equipment used at the facility.<sup>25</sup>

#### 5.5 License if a Fire Hazard

This license is required if a factory is categorized as a facility with a fire hazard. This will occur if flammable, oxidizing, explosive or combustible substances are used, remade, stored, transported or destroyed in the facility.<sup>26</sup>

A license for operating an industrial facility with a fire hazard is to be issued by the Regional Department of the Federal Service for Ecological, Technological and Nuclear Control. The main license requirements are determined by the Industrial Safety Law and are, in general, the same as those for a license for operating an industrial facility with a chemical hazard.<sup>27</sup>

State authorities and courts strictly enforce the rules in the sphere of licensing of chemical or fire hazard facilities. For example, during the first and second quarter of 2010 more than 35 facilities in the Moscow region were fined for the absence of said licenses.<sup>28</sup>

### **(6) Permits Required to Operate a Pharmaceuticals Factory**

There are many permits needed to operate a pharmaceuticals factory in Russia set forth by federal, regional and municipal legislation. The following is a list of the main permits which are required.

#### 6.1 Commissioning Act

This document confirms that the construction, reconstruction or capital repair of a factory was completed in accordance with the building permit and that the facility which was built, reconstructed, or repaired complies with the land plot layout and design documentation. The act serves as grounds for the state registration of the building.<sup>29</sup>

#### 6.2 Permit for Use of Technical Equipment

Technical equipment used at hazardous manufacturing facilities must be approved by the Federal Service for Ecological, Technological and Nuclear Control (Rostekhnadzor). A permit will be issued for each category of equipment used in a factory<sup>30</sup> on the basis of technical documentation and an industrial safety assessment.

#### 6.3 Certificate for Equipment Used

Each piece of equipment must be certified to confirm compliance with the applicable technical standards, sanitary rules, safety rules, etc. Certificates are issued by specialized certification centers in accordance with a procedure established by the law.<sup>31</sup>

#### 6.4 Report of the State Fire Inspectorate on Compliance with Fire Safety Requirements

This report is required for each industrial facility of a factory and confirms that the facility operates in compliance with all fire safety requirements, including staff readiness for necessary action in case of fire, availability of necessary quantity of fire extinguishers, a fire evacuation scheme, etc. This report is issued by the Regional Administration of the State Fire Control Authority, a part of the Ministry of the Russian Federation for Civil Defense, Emergencies and Eliminations of Consequences of Natural Disasters ("EMERCOM").<sup>32</sup>

#### 6.5 Permit for Waste Disposal

Each entity which conducts any activity resulting in generating waste should have a permit for waste disposal issued by the Regional Department of the Federal Service for Ecological, Technological and Nuclear Control in the event it is impossible to fully recycle such waste products.<sup>33</sup> A factory is obligated to seek to minimize the amount of waste products it creates and to implement waste-free technologies.<sup>34</sup>

#### 6.6 Permission for Toxic Emissions

Pursuant to federal legislation on protection of open air, any stationary industrial facilities releasing toxic emissions into the air should have a permit for toxic emissions issued by the Regional Department of the Federal Service for Ecological, Technological and Nuclear Control. Such a permit establishes a limit of toxic emissions which such facility may release.<sup>35</sup>

#### 6.7 Sanitary Examination Report

In order for the premises of a factory to operate, all production and storage premises should be provided with a sanitary expert examination report confirming compliance of the activity with the state sanitary and epidemiological rules and standards (the "SES Report"). The SES Report is issued by the Regional Departments of the Federal Service for Supervision over Customer Rights Protection and Human Welfare. The validity period of an SES report is indefinite and perpetual but it must be re-issued in the event of reorganization, rebranding or changing of location of a legal entity to which an SES Report is issued.<sup>36</sup>

#### 6.8 Fire Safety Declaration

Each building of a factory as a real estate facility requiring state expert examination of design documents and should be provided with a fire safety declaration (the "Declaration") issued by EMERCOM. The Declaration is to be provided either by owner or possessor of the facility and should contain an assessment of fire risk and evaluation of potential damage to third party property in the event of a fire.<sup>37</sup>

#### 6.9 Permit to Operate an Electric Installation

This document is required for connecting each building of a factory to the electric power network and is issued by the State Energy Control Authorities and is valid for three months. In the event a facility is not connected to the electric power network during this period, the permit will need to be re-issued.<sup>38</sup>

#### 6.10 Registration Certificates for Manufactured Goods

Each drug manufactured at a planned new facility must be registered in Russia. State registration of drugs is confirmed by a registration certificate issued by the relevant regulatory bodies.<sup>39</sup>

<sup>1</sup> The Pharmaceuticals Industry Practice Group of Capital Legal Services includes Vladislav Zabrodin, Derek Bloom, Vsevolod Tyupa, Andrei Savin, Oxana Kovaleva and Anna Shmalyuk.

<sup>2</sup> See Clause 8 Article 10 Federal Law #No.244-FZ “On Skolkovo Center of Innovations” and “Administrative Procedure of Roszdravnadzor for executing of state function for issuing of permits for using of new medical technologies approved by Order of Minzdravsocrazvitia dated 20.07.2007 № 488.

<sup>3</sup> See Federal Law No.243-FZ “On amendments to certain legislative acts of Russian Federation related to adoption of Federal Law ‘On the Skolkovo Center of Innovations’

<sup>4</sup> See Clause 4 Article 30 and Article 38 of the Land Code.

<sup>5</sup> See Clause 3 and 5 of Article 30 and Article 31 of the Land Code.

<sup>6</sup> See Article 30 of the Land Code.

<sup>7</sup> See Clause 6 Article 30 of the Land Code.

<sup>8</sup> See Clause 11 Article 30 of the Land Code.

<sup>9</sup> See Clauses 1 and 3 of Article 36 of the Land Code.

<sup>10</sup> See Clause 48 Article 17 of the Federal Law No.128-FZ “On licensing certain types of business activity in Russia” dated 08.08.2001.

<sup>11</sup> See Clause 10 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>12</sup> See Clause 2 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>13</sup> See Clause 31 Article 4 of the Federal Law No.61-FZ “On circulation of drugs” dated 12.04.2010.

<sup>14</sup> See Clause 6 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>15</sup> See Clause 7 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>16</sup> See Clause 9 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>17</sup> See Clause 4 of the Regulation on licensing the production of drugs approved by the Resolution No.684 of the Government of the Russian Federation on 03.09.2010.

<sup>18</sup> See Clause 33 Article 4 of the Federal Law No.61-FZ “On circulation of drugs” dated 12.04.2010.

<sup>19</sup> See Clause 6 of the Regulation on licensing the pharmaceutical activity approved by Resolution No.416 of the Government of the Russian Federation on 06.07.2006.

<sup>20</sup> See Clause 7 of the Regulation on licensing the pharmaceutical activity approved by the Resolution No.416 of the Government of the Russian Federation on 06.07.2006.

<sup>21</sup> See Clause 17 of Federal Law № 128-FZ “About licensing of certain types of activity” dated 08.08.2001

<sup>22</sup> See *ibid.*

<sup>23</sup> See Clause 3 of Government Order № 429 “About licensing of exploitation an industrial facility with a chemical hazard” dated 14.07.2006

<sup>24</sup> See Addendum 1 to Federal Law No.116-FZ “On industrial safety of hazardous manufacturing facilities” dated 21.07.1997

<sup>25</sup> See Federal Law No.116-FZ “On industrial safety of hazardous manufacturing facilities” dated 21.07.1997

<sup>26</sup> See Government Order № 599 “About licensing of exploitation of industrial facility with a fire hazard” dated 14.07.2006

<sup>27</sup> See Federal Law No.116-FZ “On industrial safety of hazardous manufacturing facilities” dated 21.07.1997

<sup>28</sup> See <http://www.fcao.ru/node/190>

<sup>29</sup> See Clause 55 of the Town Planning Code of the Russian Federation.

<sup>30</sup> See the Administrative Regulations on performing the state function of issuing permits to use certain types of technical equipment at hazardous manufacturing facilities, approved by Rostekhnadzor on 29.02.2008.

<sup>31</sup> See Rules for certification of production equipment, approved by the State Committee for Standardization and Metrology of the Russian Federation on 03.05.2000 and by the Resolution No.753 of the Government of the Russian Federation “On approval of the technical regulations of safety of machinery and equipment” dated 15.09.2009.

<sup>32</sup> See the Decree No.517 of the EMERCOM dated 01.10.2007.



<sup>33</sup> See Clause 2.8. of the Temporarily Rules for protection of the environment against production and consumption waste in the Russian Federation dated 15.07.1994.

<sup>34</sup> See Clause 2.3. of the Temporarily rules for protection of the environment against production and consumption waste in the Russian Federation dated 15.07.1994.

<sup>35</sup> See Clause 14 of the Federal Law No. 96-FZ “On protection of open air” dated 04.05.1999.

<sup>36</sup> See the Decree No.224 of Rospotrebnadzor “On sanitary expert examinations, inspections, researches, trials and toxic, hygienic and other types of assessment” dated 19.07.2007.

<sup>37</sup> See Article 64 of the Federal Law No.123-FZ “Technical regulations on fire safety requirements” dated 22.07.2008.

<sup>38</sup> See Items 2.1, 2.15 of the Methodical recommendations to commission electric installations dated 03.04.2002.

<sup>39</sup> See Subclause 26 Clause 4 of the Federal Law No.61-FZ “On circulation of drugs” dated 12.04.2010.