

THE RUSSIAN FEDERATION

FEDERAL LAW

**ON THE INTERNATIONAL MEDICAL CLUSTER AND AMENDING INDIVIDUAL
LEGISLATIVE ACTS OF THE RUSSIAN FEDERATION**

Passed by
the State Duma
on June, 9th 2015

Approved by
the Federation Council
on June, 24th 2015

Chapter 1. GENERAL PROVISIONS

Article 1. Subject of Regulation of the Federal Law

1. This Federal Law shall govern any relationship arising in relation with creation and provisioning for functioning of the international medical cluster.

2. The legislation of the Russian Federation shall be applicable to the relationship specified by part 1 of this article, with taking into consideration of the special aspects determined by this Federal law.

Article 2. Main Terms used in the Federal Law

For the purposes of this Federal law the following main terms shall be used:

1) the international medical cluster shall mean the aggregate infrastructure of the territory of the international medical cluster, the participants of the project and mechanisms of interaction between the participants of the project;

2) the project shall mean the aggregate of arrangements directed onto achievement of the objects of activities of the international medical cluster;

3) the infrastructure of the territory of the international medical cluster shall mean the aggregate territory of the international medical cluster and any buildings, constructions, structures and other facilities within it, including any facilities of the communal infrastructure;

4) a participant of the project shall mean any legal entity, individual entrepreneur or a foreign legal entity or individual entrepreneur established and registered in accordance with legislation of a foreign country being a member of the Organization for Economic Cooperation and Development (hereinafter, "the OECD member"), which concluded an agreement on implementation of the project with the managing company (hereinafter, "the agreement");

5) a foreign expert shall mean a foreign citizen engaged by a participant of the project for labor activity for the purposes of implementation of the project;

6) the managing company shall mean a Russian legal entity created in a legal organizational form of a foundation by resolution of the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status, for the purposes of provisioning for functioning of the international medical cluster and management thereof.

Article 3. Objects of Activities of the International Medical Cluster

The international medical cluster shall be created within the territory determined by the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status, for the purposes of development of medical activities on provision of medical care with enhancement of quality thereof, assistance in development of medicinal drugs for medical use (hereinafter, "the medicinal drugs"), medical technologies and medical products, development of education activities and carrying out of scientific research in the sphere of healthcare and with purposes of international cooperation in said sphere of activities.

Chapter 2. MANAGEMENT OF THE INTERNATIONAL MEDICAL CLUSTER

Article 4. Managing Company of the International Medical Cluster

1. The status, objects of activities, functions of the managing company of the international medical cluster (hereinafter, "the managing company") and the procedure of establishing of its management bodies shall be determined by this Federal law, the Federal law of January, 12th 1996 No. 7-ФЗ "On Non-Commercial Organizations", other normative legal acts of the Russian Federation governing activities of non-commercial organizations, with taking into consideration of the special aspects determined by this Federal law.

2. The managing company shall provide for methodological, organizational, forensic and analytical and informational support of activities of the international medical cluster.

3. The managing company shall perform the following functions:

1) executes the agreement with a legal entity, individual entrepreneur wishing to receive the status of a participant of the project, refuses to execute such agreement, terminates the agreement with any participant of the project, on the basis of a resolution passed by the supervisory board;

2) keeps of a register of participants of the project (hereinafter, "the register"), publishes the register on the web-site of the international medical cluster on the Internet information and telecommunications network (hereinafter, "the Internet");

3) organizes provision to the participants of the project of any services necessary for performance of activities thereof on implementation of the project (including legal and consulting services, accounting services);

4) coordinates activities of the participants of the project, provides for interaction of the participants of the project;

5) organizes training and probation of staff on behalf of the participants of the project, as well as provision of additional professional education;

6) assists the participants of the project in products and services market promotion, as well as in development of scientific and technical cooperation of the participants of the project, including cooperation with any foreign organizations;

7) in the order established by the Government of the Russian Federation, submits to a federal executive authority authorized by the Government of the Russian Federation a notification on beginning of performance by the participants of the project of any medical activities on provision of medical care within the territory of the international medical cluster, including data on applied rules, requirements, regulations and guidelines, on any medicinal drugs and medical products being used;

8) provides for registration of rights to results of intellectual activities and individualization means, including state registration thereof in cases prescribed by the legislation of the Russian Federation;

9) performs control over compliance of activities of the participants of the project with the objects of activities of the international medical cluster and the requirements of this Federal law, in the order approved by the supervisory board of the managing company;

10) establishes consultative and advisory bodies;

11) provides for activities of the expert board of the managing company;

12) organizes carrying out of any other arrangements in accordance with the objects of activities of the international medical cluster.

4. The managing company's management bodies shall be the supervisory board, the management board and the general director.

5. Financial support of activities of the managing company shall be performed on account of own

costs of the managing company, budget costs of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status, as well as from any other sources in accordance with the legislation of the Russian Federation.

6. The managing company shall be obliged to publish annual report on its activities and annual reports of the participants of the project on results of activities thereof within the territory of the international medical cluster on the official web-site of the international medical cluster on the Internet.

Article 5. The Supervisory Board of the Managing Company

1. The supervisory board of the managing company shall be the supreme management body of the managing company.

2. The supervisory board of the managing company shall perform general management of the managing company's activities and control thereof.

3. Regulations on the supervisory board of the managing company, its composition and procedure of establishment shall be determined by the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status.

4. The supervisory board of the managing company shall exercise the following authorities:

1) determines priority areas of activities of the international medical cluster;

2) approves criteria of selection of legal entities, individual entrepreneurs wishing to receive the status of a participant of the project;

3) approves upon agreement with the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status, the procedure of decision making on executing of the agreement, on termination of such agreement, including early termination thereof;

4) passes resolutions on executing by the managing company of the agreement with a legal entity, individual entrepreneur wishing to receive the status of a participant of the project, on refusal to execute the agreement and termination of the agreement;

5) approves financial plan of the managing company, its annual report and annual accounting balance;

6) approves forms of documents required for performance of functions of the managing company;

7) approves regulations on the management board of the managing company;

8) approves regulations on the expert board of the managing company, its compositions and procedure of establishment, determines tasks and functions of any other consultative and advisory bodies of the managing company;

9) approves the procedure of expertise prescribed by part 3 of article 8 of this Federal law;

10) approves the procedure of control by the managing company of compliance of activities of the participants of the project with the objects of activities of the international medical cluster, as well as with requirements of this Federal law;

11) hears annual reports of the participants of the project on results of activities thereof within the territory of the international medical cluster;

12) executes any other authorities determined by this Federal law, other federal laws and regulations on the supervisory board of the managing company.

Article 6. The Management Board of the Managing Company

1. The management board of the managing company shall be the collective executive body of the managing company and shall consist of the general director of the managing company being a member of the management board by virtue of his position and of other members of the management board.

2. Members of the management board of the managing company shall be appointed and their appointment shall be terminated by the supervisory board of the managing company upon the recommendation of the general director.

3. The management board of the managing company shall perform its activities on the basis of regulations on the management board of the managing company.

4. The management board of the managing company shall exercise the following authorities:

1) provides for consideration of any applications, permission documentation and other documents provided by any legal entity, individual entrepreneur wishing to receive the status of a participant of the

project, in accordance with part 3 of article 9 of this Federal law;

2) refers for consideration of the supervisory board of the managing company a proposal on early termination of an agreement in cases prescribed by part 9 of article 9 of this Federal law;

3) approves the procedure of informational support of the managing company's activities, including maintenance of the official web-site of the international medical cluster on the Internet;;

4) passes resolutions on issues of coordination and provision for interaction of the participants of the project;

5) agrees conditions of use by the participants of the Project of infrastructure of the international medical cluster;

6) exercises any other authorities prescribed by this Federal law, regulations on the management board of the managing company and resolutions of the supervisory board thereof.

Article 7. The General Director of the Managing Company

1. The general director of the managing company shall perform management of current activities of the managing company.

2. The general director of the managing company shall be appointed and authorities thereof may be terminated by the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status as may be agreed with the supervisory board of the managing company.

3. The general director of the managing company shall exercise the following authorities:

1) acts on behalf of the managing company and represent its interests without power of attorney in relations with federal authorities, state authorities of constituent entities of the Russian Federation, local authorities, international organizations and other organizations;

2) manages activities of the management board of the managing company;

3) provides for execution of resolutions passed by the supervisory board of the managing company;

4) issues orders and instructions on matters related to activities of the managing company;

5) appoints and dismisses employees of the managing company;

6) assigns obligations to the deputies thereof;

7) provides for preparation of materials for exercising by the supervisory board and the management board of the managing company of their authorities and considers any other issues related to support of activities of the supervisory board, the management board and the expert board of the managing company, any other consultative and advisory bodies;

8) passes resolutions and acts on any other issues of activities of the managing company, excluding any issues referred to the competence of the supervisory board and the management board thereof.

Article 8. The Expert Board of the Managing Company

1. The expert board of the managing company shall be the permanently acting consultative body.

2. The expert board of the managing company shall be established from representatives of community of professionals performing medical, educational or scientific activities in the sphere of healthcare, having relevant professional experience of at least ten years, having professional qualification and unblemished reputation.

3. The expert board of the managing company shall carry out an expertise of any arrangements proposed by a legal entity, individual entrepreneur wishing to receive the status of a participant of the project for implementation within the territory of the international medical cluster, and on results thereof shall prepare its expert opinion on compliance of such arrangements with the object of activities of the international medical cluster, significance, scientific validation, economic feasibility and practical feasibility thereof.

4. The expert board of the managing company shall have the right to provide the supervisory board of the managing company with proposals on making of amendments to the register.

5. The expert board of the managing company shall perform other functions specified by regulation on the expert board of the managing company and resolutions of the supervisory board of the managing company.

BY THE PARTICIPANTS OF THE PROJECT

Article 9. Receiving of the Status of a Participant of the Project and Special Aspects of Activities of the Participants of the Project

1. A legal entity, individual entrepreneur shall receive the status of a participant of the project as of the date of executing of the agreement with the managing company.

2. Material terms of the agreement shall be compliance with the rules and requirements specified by sub-clause "e" of clause 3 of part 3 of this article, liability insurance for a participant of the project and (or) medical staff providing medical care within the territory of the international medical cluster.

3. For closing of the transaction such legal entity, individual entrepreneur wishing to receive the status of a participant of the project shall provide the managing company with:

1) application for exercising of the agreement;

2) instruments of incorporation providing for performance of any activities complying with the objects of activities of the international medical cluster (for legal entities);

3) description of the arrangements proposed to be carried out within the territory of the international medical cluster with specification of:

a) main purposes of participation in the project and anticipated results of carrying out of the project arrangements;

b) data on planned types of activities within the territory of the international medical cluster;

c) data on experience in performance of said types of activities during at least three years;

d) data on significance, scientific, economical and practical feasibility of proposed arrangements;

e) data on developments, methods, technologies, including innovations, on rules and requirements of provision of medical care applicable in a foreign state being the OECD member issuing permissions to perform medical activity to a participant of the project and which are to be applied within the territory of the international medical cluster;

4) any documents issued within the territory of the Russian Federation and confirming the right to perform specified types of activities (for Russian legal entities, individual entrepreneurs) or any permissions issued in the established order by competent authorities and organizations of a foreign state being the OECD member and confirming the right to perform specified types of activities (for foreign legal entities, individual entrepreneurs);

5) registration certificates for any medicinal drugs, registration certificate for any medical products which are planned to be used within the territory of the international medical cluster (for Russian legal entities, individual entrepreneurs) or any permissions (including registrations, regulations and other documentation) for any medicinal drugs, medical products and medical technologies which are planned to be used within the territory of the international medical cluster, as well as results of testing of any medical products, patents, other medical and technical documents, issued in the established order by competent authorities and organizations of a foreign state being the OECD member (for foreign legal entities, individual entrepreneurs);

6) any documents confirming educational degrees and (or) qualification of any experts engaged for implementation of the project;

7) rights, rules, regulations and norms of any foreign states being the OECD members specified by part 2 or article 15 and part 1 of article 16 of this federal law and which are to be used within the territory of the international medical cluster.

4. Any documents executed in a foreign language shall be provided to the managing company by a legal entity, individual entrepreneur wishing to receive the status of a participant of the project with translation thereof into Russian with certification in the order established by the legislation of the Russian Federation.

5. The managing company shall within forty five working days consider said application and other documents being provided by a legal entity, individual entrepreneur wishing to receive the status of a participant of the project and shall determine completeness and correctness of execution thereof.

6. On results of consideration of provided documents and with taking into consideration of results of the expertise provided by part 3 of article 8 of this Federal law, and on the basis of a resolution passed by the supervisory board thereof, the managing company shall either conclude the agreement with said legal entity, individual entrepreneur wishing to receive the status of a participant of the project, or refuse

to conclude such agreement.

7. The managing company shall within ten working days as of passing of the resolution specified by part 6 of this article notify such legal entity, individual entrepreneur on the resolution being passed.

8. A legal entity, individual entrepreneur shall lose their status of a participant of the project upon expiration of ten years of the date of conclusion of the agreement or as of the date of preliminary termination of the agreement, liquidation or reorganization of the legal entity being a participant of the project (excluding its reorganization in form of transformation, merger or accession if each of the legal entities participating in such transformation, merger or accession of the status of a participant of the project as of the date of state registration of the legal successor of the legal entity being reorganized), termination of activities of an individual entrepreneur.

9. A resolution on early termination of the agreement may be passed in the following cases:

- 1) refusal of a participant to participate in the project;
- 2) performance by a participant of the project of any activity not complying with the objects of activities of the international medical cluster;
- 3) repeated infringement of the agreement by a participant of the project;
- 4) non-compliance by a participant of the project with the requirements established by part 10 of this article.

10. A participant of the project shall be obliged to assist the managing company in control over implementation of the agreement, including granting of an unimpeded access of any officers of the managing company belonging to its infrastructure facilities within the territory of the international medical cluster, provide the managing company in writing with any information required for performance of control, including annual reports on results of its activities within the territory of the international medical cluster.

11. Information of conclusion and termination of the agreement, inclusion of a participant into the register or striking it off the register shall be published by the managing company on the official website of the international medical cluster on the Internet within three days of conclusion or termination of the agreement.

Article 10. Liability

Non-compliance by the participants of the project of any rules, requirements, regulations and norms established and (or) applied within the territory of the international medical cluster in accordance with this Federal law, including resulting in inflicting harm onto health and (or) life of any persons, material damage, shall be recognized as a breach of the legislation of the Russian Federation and shall involve liability in accordance with the legislation of the Russian Federation.

Article 11. Procedure of Disputes settlement During Implementation of the Agreement

Any disputes related to implementation of the agreement shall be settled by judicial procedure in accordance with the legislation of the Russian Federation.

Chapter 4. SPECIAL ASPECTS OF REGULATION OF CERTAIN RELATIONSHIP DURING IMPLEMENTATION OF THE AGREEMENT

Article 12. Recognition within the Territory of the International Medical Cluster of any Permissions, Academic Credentials and (or) Qualifications Certificates Issued by Competent Authorities and Organizations of a Foreign State Being the OECD Member

1. Any permissions specified by clauses 4 and 5 of part 3 of article 9 of this Federal law and issued in the established order by competent authorities and organizations of a foreign state being the OECD member to the participants of the project shall be recognized within the territory of the international medical cluster as well as any permissions issued in the Russian Federation.

2. Any academic credentials and (or) qualifications certificates of foreign experts issued in the established order by competent authorities and organizations of a foreign state being the OECD member shall be recognized as valid within the territory of the international medical cluster.

Article 13. Special Aspects of Performance of Medical Activity within the Territory of the International Medical Cluster

1. The participants of the project providing medical care shall have the right to use:

1) any medicinal drugs and medical products registered in the established order by competent public authorities, competent organizations in the Russian Federation or a foreign state being the OECD member and applicable in the country of registration thereof;

2) any rules and requirements applicable in the Russian Federation and (or) in a foreign state being the OECD member in which a participant was given the permissions specified by clauses 4 and 5 of part 3 of article 9 of this Federal law.

2. Obligatory precondition of provision of medical care shall be provision of informed voluntary consent by a citizen (legal representative thereof) for medical intervention on the basis of submitted by medical staff of complete information in an intelligible form on the purposes and methods of provision of medical care, including information on medicinal drugs and medical products registered in a foreign state being the OECD member, related risks, possible variants of medical intervention, consequences thereof and anticipated results of provision of such medical care.

3. During provision of medical care within the territory of the international medical cluster the participants of the project shall have all rights granted to any medical organizations which obtained appropriate licenses in accordance with legislation of the Russian Federation.

4. Only the participants of the project having permissions for performance of medical care issued in the Russian Federation may be engaged to provision of medical care paid for out of costs of budgeting system of the Russian Federation, including costs of territorial compulsory medical insurance funds.

Article 14. Special Aspects of Employment of Foreign Experts

1. The participants of the project acting as employers shall engage and use any foreign experts in the order and on terms provided for appropriate categories of foreign citizens by the Federal law of July, 25th 2002 No. 115-Ф3 "On Legal Status of Foreign Citizens in the Russian Federation", with taking into consideration of the following aspects:

1) obtaining by a participant of the project acting as an employer of any permission for engagement and use of any foreign experts being medical, educational or scientific staff shall not be required;

2) invitations for entry into the Russian Federation and work for any foreign experts shall be issued without any quotas determined by the Federal law of July, 25th 2002 No. 115-Ф3 "On Legal Status of Foreign Citizens in the Russian Federation";

3) execution of said invitations for entry into the Russian Federation and work for any foreign experts specified by clause 1 of this article shall be made through the managing company.

2. Permissions to work for any foreign experts shall be issued for a term of concluded with them labor contracts or civil law contracts for performance of works (provision of services), but not exceeding three years as of the date of entry by a foreign specialist into the Russian Federation with possibility of further recurrent prolongation of such permission for a term not exceeding three years. The permission to work grants to foreign experts the right to perform labor activity only for the project implementation.

3. The form of a permission to work issued to foreign experts shall be established by a federal executive authority authorized for performance of migration control and monitoring functions.

Article 15. Special Aspects of Technical Regulation within the Territory of the International Medical Cluster

1. Any activity within the territory of the international medical cluster shall be performed in compliance with safety requirements, including fire safety regulations, requirements to products or related to products processes of designing (including surveying), manufacturing, construction, assembly, adjustment, use, storage, transportation, sale and disposal in part of compliance with appropriate technical regulations or before their coming into effect – with normative legal acts of the Russian Federation and normative documents of federal executive authorities, excluding cases determined by this article.

2. In relation to any products used within the territory of the international medical cluster or related to products processes of designing (including surveying), manufacturing, construction,

assembly, adjustment, use, storage, transportation, sale and disposal, instead of separate safety requirements contained in appropriate technical regulations or before their coming into effect – in normative legal acts of the Russian Federation and normative documents of federal executive authorities, or in case of absence of such requirements and regulations, there may be applied the technical regulations or requirements of different regulations and documents of any foreign states being the OECD members applicable in such foreign states and specified by a participant of the project for use during performance of its activities within the territory of the international medical cluster in accordance with clause 7 of part 3 of article 9 of this Federal law.

3. Information on any documents specified by part 2 of this article and applicable within the territory of the international medical cluster in the order established by the Government of the Russian Federation shall be submitted by the managing company to the federal executive authority performing functions of provisioning of services in the sphere of technical regulation and ensuring the uniformity of measurements, the federal executive authority performing functions of development and implementation of state policies and regulation in the sphere of construction, architecture, urban development (excluding territorial planning) and housing and utilities infrastructure and shall be published on the official web-site of the international medical cluster on the Internet.

4. The safety requirements, including fire safety regulations, contained in the documents specified by part 2 of this article shall be applicable within the territory of the international medical cluster as of the date of submission of the information specified by part 3 of this article to the federal executive authority authorized by the Government of the Russian Federation.

5. In case of application within the territory of the international medical cluster of the documents specified by part 2 of this article, an obligatory compliance verification shall not be carried out, excluding state control (supervision). Said state control (supervision) shall in this case be performed with taking into consideration of the provisions of part 6 of this article.

6. In case of application within the territory of the international medical cluster of the documents specified by part 2 of this article, the subject of said state control (supervision) shall be verification of compliance with the safety requirements, including fire safety regulations, prescribed by such documents.

Article 16. Special Aspects of Sanitary and Epidemiological Welfare of the Population within the Territory of the International Medical Cluster

1. Within the territory of the international medical cluster there may be applied the sanitary and epidemiological rules and hygienic standards or requirements of sanitary and epidemiological regulations or documents of any foreign states being the OECD members applicable in such foreign states and specified by a participant of the project for use.

2. Application within the territory of the international medical cluster of the sanitary and epidemiological rules and hygienic standards or requirements specified in part 1 of this article shall provide for exclusion of any harmful effects of environmental conditions in relation to population. Any safety criteria established by said rules and standards or requirements shall comply with the standards, recommendations, guidelines and other documents applied by international organizations.

3. Information on the sanitary and epidemiological rules and hygienic standards or requirements specified in part 1 of this article and applicable within the territory of the international medical cluster in the order established by the Government of the Russian Federation shall be submitted by the managing company to the federal executive authority performing functions of control and supervision over sanitary and epidemiological welfare of the population and shall be published on the official web-site of the international medical cluster on the Internet.

4. The sanitary and epidemiological rules and hygienic standards or requirements specified in part 1 of this article shall be applicable within the territory of the international medical cluster as of the date of submission of the information thereon to the federal executive authority authorized to perform functions of control and supervision over sanitary and epidemiological welfare of the population.

5. In case of application within the territory of the international medical cluster of the documents specified by part 1 of this article the subject of the federal state sanitary and epidemiological supervision shall be verification of compliance with the sanitary and epidemiological rules and hygienic standards or requirements prescribed by such documents.

Article 17. Special Aspects of Regulation of Urban Development within the Territory of the International Medical Cluster

1. The development plan of the territory of the international medical cluster shall be prepared by the managing company and shall be approved by the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status.

2. Any public hearing as to the development plan of the territory of the international medical cluster shall not be carried out.

3. Within the territory of the international medical cluster by the supreme government organ of a constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status, there may be established:

1) any special aspects of provision of technical conditions of connection (technological connection) to facilities of electricity supply network of power receivers of electrical users, determination of payment for such connection (technological connection), special aspects of such connection (technological connection);

2) any special aspects of provision of technical conditions of connection (technological connection) of a permanent facility to networks of heat, gas and water supply, determination of payment for such connection (technological connection), special aspects of such connection (technological connection).

4. Preparation of the development plan of the territory of the international medical cluster, planning documentation, construction, reconstruction, capital repair of any permanent facilities within the territory of the international medical cluster, use of buildings, constructions, structures located within the territory of the international medical cluster may be performed in accordance with requirements of technical regulations or with requirements of technical regulations or documents of any foreign states being the OECD members and in accordance with sanitary and epidemiological rules and hygienic standards or requirements of sanitary and epidemiological regulations or documents of any foreign states being the OECD members, with taking into consideration of the provisions prescribed by articles 15 and 16 of this Federal law. In case of performance of state control (supervision) in the process of construction, reconstruction, capital repair of any permanent facilities within the territory of the international medical cluster, use of buildings, constructions, structures located within such territory, there shall be applied the requirements of technical regulations or documents of any foreign states being the OECD members, as well as the sanitary and epidemiological rules and hygienic standards or requirements of sanitary and epidemiological regulations or documents of any foreign states being the OECD members.

Chapter 5. FINAL PROVISINS

Article 18. On Amending of the Federal Law "On Fire Safety"

Article 20 of the Federal law of December, 21st 1994 No. 69-Ф3 "On Fire Safety" (Legislation Bulletin of the Russian Federation, 1994, No. 35, p. 3649; 2004, No. 35, p. 3607; 2009, No. 45, p. 5265; 2010, No. 40, p. 4969; 2011, No. 30, p. 4596) shall be amended by adding of part seven as follows:

"The special aspects of ensuring the fire safety within the territory of the international medical cluster, including any special aspects of application of safety requirements (including requirements of technical regulations) shall be determined by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".".

Article 19. On Amending of the Federal Law "On Sanitary and Epidemiological Welfare of the Population"

Article 2 of the Federal law of March, 30th 1999 No. 52-Ф3 "On Sanitary and Epidemiological Welfare of the Population" (Legislation Bulletin of the Russian Federation, 1999, No. 14, p. 1650; 2004, No. 35, p. 3607; 2010, No. 40, p. 4969; 2011, No. 30, p. 4590, 4596) shall be amended by adding of clause 4 as follows:

"4. The special aspects of ensuring the sanitary and epidemiological welfare of the population within the territory of the international medical cluster, including any special aspects of application of sanitary and epidemiological requirements, shall be determined by the Federal act "On the International

Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".

Article 20. On Amending of the Federal Law "On legal Status of Foreign Citizens in the Russian Federation"

To amend the Federal law of July, 25th 2002 No. 115-Ф3 "On legal Status of Foreign Citizens in the Russian Federation" (Legislation Bulletin of the Russian Federation, 2002, No. 30, p. 3032; 2006, No. 30, p. 3286; 2007, No. 2, p. 361; No. 49, p. 6071; 2008, No. 30, p. 3616; 2009, No. 19, p. 2283; 2010, No. 21, p. 2524; No. 40, p. 4969; No. 52, p. 7000; 2011, No. 13, p. 1689; No. 17, p. 2321; No. 27, p. 3880; No. 49, p. 7043, 7061; 2012, No. 53, p. 7645; 2013, No. 19, p. 2309; No. 23, p. 2866; No. 27, p. 3477; No. 30, p. 4036, 4037, 4081; No. 52, p. 6955; 2014, No. 19, p. 2311, 2332; No. 26, p. 3370; No. 48, p. 6638, 6659; No. 49, p. 6918; 2015, No. 1, p. 61, 72; No. 10, p. 1426; No. 21, p. 2984) as follows:

1) in article 13:

a) sub-clause 8.3 of shall be added to clause 4 as follows:

"8.3) invited to the Russian Federation as medical, educational or scientific staff in case of invitation thereof for performance of appropriate activities within the territory of the international medical cluster;"

b) clause 4.12 shall be added as follows:

"4.12. The special aspects of performance by any foreign citizens of their labor activity within the territory of the international medical cluster shall be determined by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".

2) sub-clause 1.2 shall be added to clause 1 of article 13.2 as follows:

"1.2) in amount not exceeding RUR one million for one year (365 calendar days) for highly trained professionals of medical, educational or scientific staff in case of invitation thereof for performance of appropriate activities within the territory of the international medical cluster;"

Article 21. On Amending of the Federal Law "On Technical Regulation"

Chapter 1 of the Federal law of December, 27th 2002 No. 184-Ф3 "On Technical Regulation" (Legislation Bulletin of the Russian Federation, 2002, No. 52, p. 5140; 2007, No. 19, p. 2293; No. 49, p. 6070; 2009, No. 29, p. 3626; 2010, No. 1, p. 5, 6; No. 40, p. 4969; 2011, No. 30, p. 4603; No. 49, p. 7025; 2012, No. 50, p. 6959; 2014, No. 26, p. 3366) shall be amended by adding of article 5.3 as follows:

"Article 5.3. Special Aspects of Technical Regulation in the Sphere of Ensuring of Safety of Products as well as of the Processes of Designing (including Surveying), Manufacturing, Construction, Assembly, Adjustment, Use, Storage, Transportation, Sale And Disposal Applicable within the Territory of the International Medical Cluster

The special aspects of technical regulation in the sphere of ensuring of safety of products as well as of the processes of designing (including surveying), manufacturing, construction, assembly, adjustment, use, storage, transportation, sale and disposal applicable within the territory of the international medical cluster shall be determined by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".

Article 22. On Amending of the Federal Law "On Electric Power Industry"

To amend article 2 of the Federal act of March, 26th 2003 No. 35-Ф3 "On Electric Power Industry" (Legislation Bulletin of the Russian Federation, 2003, No. 13, p. 1177) as follows:

1) the words "the legislation of the Russian Federation" shall be replaced by the words "1. The legislation of the Russian Federation";

2) clause 2 shall be added as follows:

"2. The legislation of the Russian Federation on electric power industry in relation to the legal entities and individual entrepreneurs performing their activities within the territory of the international medical cluster shall be applicable with taking into consideration of any special aspects established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".

Article 23. On Amending of the Federal Law "On Enactment of the Urban Planning Code of the Russian Federation"

The Federal law of December, 29th 2004 No. 191-Ф3 "On Enactment of the Urban Planning Code of the Russian Federation" (Legislation Bulletin of the Russian Federation, 2005, No. 1, p. 17; No. 30, p. 3122; 2006, No. 1, p. 17; No. 27, p. 2881; No. 52, p. 5498; 2007, No. 21, p. 2455; No. 49, p. 6071; No. 50, p. 6237; 2008, No. 20, p. 2251; No. 30, p. 3604; 2009, No. 1, p. 19; No. 11, p. 1261; No. 19, p. 2283; No. 29, p. 3611; No. 48, p. 5723; No. 52, p. 6419, 6427; 2010, No. 31, p. 4209; No. 40, p. 4969; No. 52, p. 6993; 2011, No. 13, p. 1688; No. 30, p. 4563, 4594; 2012, No. 26, p. 3446; No. 27, p. 3587; No. 53, p. 7614, 7615; 2013, No. 14, p. 1651; No. 23, p. 2866; No. 30, p. 4072; No. 52, p. 6976; 2014, No. 26, p. 3377; 2015, No. 1, p. 9, 38, 52, 72; No. 9, p. 1195; No. 10, p. 1418; No. 17, p. 2477) shall be amended by adding of article 10.8 as follows:

"Article 10.8

Performance of any urban planning activities within the territory of the international medical cluster shall be regulated by the Urban Planning Code of the Russian Federation with taking into consideration of any special aspects established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".

Article 24. On Amending of the Federal Law "On Circulation of Medicinal Drugs"

The Federal law of April, 12th 2010 No. 61-Ф3 "On Circulation of Medicinal Drugs" (Legislation Bulletin of the Russian Federation, 2010, No. 16, p. 1815; 2011, No. 50, p. 7351) shall be amended as follows:

1) part 1.1 shall be added to article 3 as follows:

"1.1. The legislation on circulation of medicinal drugs in relation to the legal entities and individual entrepreneurs performing their activities within the territory of the international medical cluster shall be applicable with taking into consideration of any special aspects established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".";

2) in article 50:

a) the name shall be added with the words ", as well as for use within the territory of the international medical cluster";

b) clause 6 shall be added to part 1 as follows:

"6) use within the territory of the international medical cluster."

Article 25. On Amending of the Federal Law "On Skolkovo Innovation Centre"

The Federal law of September, 28th 2010 No. 244-Ф3 "On Skolkovo Innovation Centre" (Legislation Bulletin of the Russian Federation, 2010, No. 40, p. 4970; 2011, No. 29, p. 4300; 2013, No. 52, p. 7005; 2015, No. 21, p. 2987) shall be amended as follows:

1) in article 3:

a) part 2 shall be amended as follows:

"2. There shall not be allowed to dispose of the land plots located within the territory of the Centre and beneficially owned by the managing company, including by the way of alienation and encumbrance thereof, excluding cases of transfer thereof by the managing company on lease to the persons participating in the project implementation with the purposes of implementation thereof or to any other persons in accordance with article 20.1 of this Federal law. Thereby, said land plots may be subleased.";

b) part 5 shall be amended as follows:

"5. The procedure and terms of provision of the land plots located within the territory of the Centre and beneficially owned by the managing company on lease to the persons participating in the project implementation with the purposes of implementation thereof or to any other persons in accordance with article 20.1 of this Federal law shall be determined by the rules of the project with taking into consideration of the provisions of this article.";

2) article 20.1 shall be added to chapter 6 as follows:

"Article 20.1. Special Aspects of Regulation of Activities on Establishment and Provisioning for Functioning of the International Medical Cluster within the Territory of the Centre

1. The land plots located within the territory of the Centre and beneficially owned by the managing company may be provided by the managing company on lease with the purposes of establishment and provisioning for functioning of the international medical cluster.

2. In case of location of the international medical cluster within the land plots located within the territory of the Centre, provided on lease with the purposes of establishment and provisioning for functioning of the international medical cluster and included into the territory of the international medical cluster, this Federal law shall be applicable to the relationship related to establishment and provisioning for functioning of the international medical cluster in cases and in the order prescribed by this article.

3. In case of inclusion of the land plots specified by part 1 of this article into the territory of the international medical cluster in the order established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation":

1) any outdoor advertising within the land plots included into the territory of the international medical cluster shall be placed and distributed of in accordance with article 12 of this Federal law;

2) the managing company shall have the right to provide to the participants of the project of the international medical cluster the services of a customs broker (representative) in relation to any goods (excluding any excisable goods) imported with the purposes of use thereof for construction, customizing and equipment of items of immovable property within the territory of the international medical cluster on required for performance of any activities in compliance with the objects of activities of the international medical cluster;

3) any educational activities within the territory of the international medical cluster shall be performed of in accordance with article 17 of this Federal law;

4) any facilities of engineering and (or) transport infrastructure of the territory of the Centre may be used with the purposes of establishment and provisioning for functioning of the international medical cluster. The procedure and terms of use of said facilities of engineering and (or) transport infrastructure of the territory of the Centre may be determined by the managing company and by the constituent entity of the Russian Federation, and namely – of a city of Moscow with federal status.

4. Any relationship related to establishment and provisioning for functioning of the international medical cluster within the borders of the land plots specified by part 1 of this article and not specified by part 3 of this article shall be regulated by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation" and other legislative acts of the Russian Federation."

Article 26. On Amending of the Federal Law "On Licensing of Certain Types of Activity"

Article 1 of the Federal law of May, 4th 2011 No. 99-Φ3 "On Licensing of Certain Types of Activity" (Legislation Bulletin of the Russian Federation, 2011, No. 19, p. 2716; No. 48, p. 6728; 2013, No. 27, p. 3477; 2014, No. 30, p. 4256; No. 42, p. 5615; 2015, No. 1, p. 11, 72) shall be amended by adding of part 6 as follows:

"6. The provisions of this Federal law shall be applicable to the relationship related to licensing of activities of the organizations located within the territory of the international medical cluster and performing any activities complying with directions of activities of the international medical cluster with taking into consideration of any special aspects established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation"."

Article 27. On Amending of the Federal Law "On Fundamental Healthcare Principles in the Russian Federation"

The Federal law of November, 21st 2011 No. 323-Φ3 "On Fundamental Healthcare Principles in the Russian Federation" (Legislation Bulletin of the Russian Federation, 2011, No. 48, p. 6724; 2013, No. 48, p. 6165; 2015, No. 1, p. 72, 85) shall be amended as follows:

1) part 7 shall be added to article 3 as follows:

"7. The legislation in the sphere of healthcare in relation to the organizations located within the territory of the international medical cluster and performing medical activities shall be applicable with taking into consideration of any special aspects established by the Federal act "On the International Medical Cluster and Amending Individual Legislative Acts of the Russian Federation".";

2) part 5 of article 38 shall be amended as follows:

"5. Any medical products manufactures by individual order of any patients and facing special requirements on appointment of medical staff, which are designed for personal use by a certain patient only, as well as any medical products for use within the territory of the international medical cluster shall not be subjected to state registration. Provisions of part 3 of this article providing for development by the manufacturer (producer) of any medical product of technical and (or) operating documentation shall not be applicable to such medical products."

Article 28. On Amending of the Federal Law "On Education in the Russian Federation"

Part 8 of article 4 of the Federal law of December, 29th 2012 No. 273-Ф3 " On Education in the Russian Federation " (Legislation Bulletin of the Russian Federation, 2012, No. 53, p. 7598; 2015, No. 1, p. 72) shall be amended as follows:

"8. The legislation on education in relation to M.V. Lomonosov Moscow State University, Sankt-Petersburg State University and the organizations located within the territory of the Skolkovo Innovation Centre, within the territory of the international medical cluster, within the territories of advanced social and economic development and performing educational activities shall be applicable with taking into consideration of the special aspects determined by special federal laws."

Article 29. Enactment of this Federal law

This Federal law shall come into force as of the date of official publication thereof.

President of
the Russian Federation
V. PUTIN

Moscow, the Kremlin
June, 29th 2015
No. 160-Ф3
