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Registration of Medical Devices in Russia: Recent Changes

The Government of the Russian Federation by its Resolution No. 633, dated 31 May 2018 introduced changes to the Rules for the State Registration of Medical Devices approved by Resolution of the Government No. 1416, dated 27 December 2012 (hereinafter - the '**Registration Rules**').

The changes are aimed at reducing the timing of state registration of certain types of medical devices, bringing the requirements for documents confirming the quality of a medicine and pharmaceutical substance contained in the medical device, as well as the procedure for making changes to the registration certificate and registration dossier for a medical device in line with the requirements of the Eurasian Economic Union (EAEU).

1. Documents Required for State Registration of a Medical Device

The list of documents that must be submitted for the state registration of medical devices was expanded and now includes, in particular:

- for medical devices of foreign origin – information on permits issued by the registering authority for their import for the purpose of their state registration;

- copies of documents confirming the quality of a medicine, pharmaceutical substance, biological material and other substance used in manufacturing of the medical device or being a part of it and intended for use only for the purpose of the medical device specified by the manufacturer, and issued in accordance with legislation of the country of origin.

However, information confirming the clinical efficiency and safety of medical devices now need to be submitted only for medical devices of the 1-class potential risk of use and medical devices for in vitro diagnostics.

2. Expert Appraisal of Quality, Efficiency and Safety a Medical Device

The first stage shall involve an examination of the registration application and other documents to determine the possibility (impossibility) of conducting clinical trials of a medical device, except for medical devices of the 1-class potential risk of use and medical devices for in vitro diagnostics.

The timing of registration of medical devices of the 1-class potential risk of use (low risk) and medical devices for in vitro diagnostics was thus reduced down to 20 business days due to conducting of the expert appraisal of quality, efficiency and safety in a single stage without the need to obtain a permit for clinical trials.

In the event during the expert appraisal the registering authority identifies in the document submitted by the applicant in response to the request inaccurate and/or inadequate information or documents compiled or containing the text in a foreign language without translation in Russian in the established procedure, the registration authority shall within 2 business days send a decision on return of such documents and a notice on the option of re-submission of finalised documents within 50 business days from the day of request thereof. If the applicant fails to provide the requested materials and information within the specified period, the expert appraisal of quality, efficiency and safety of the medical device shall continue with the available documents and information contained in the registration dossier.

3. Clinical Trials

Clinical trials of a medical device are conducted on the basis of a permit for clinical trials issued by the registering authority, as well as an opinion on the ethical validity of clinical trials issued by the Ethics Board of the Ministry of Health of the Russian Federation, except for medical devices of the 1-class potential risk of use and medical devices for in vitro diagnostics.

Upon completion of clinical trials and submission by the applicant to the registering authority of an application for the renewal of state registration of the medical device, results of clinical trials of the medical device and other required documents, the registering authority after checking the completeness and reliability of information contained therein shall decide on the renewal of state registration of the medical device.

Where these documents are not provided in full or contain inadequate data, as well as where the documents submitted were made in a foreign language without Russian translation certified in accordance with the established procedure, the registering authority shall send the applicant a decision to return the application for renewal of state registration of the medical device. The applicant may re-submit the application enclosing polished documents.

4. Making Changes to the Registration Dossier

The list of information, which can be changed within the documents contained in the registration dossier without the quality, efficiency and safety control for the medical device now includes:

1) applicant's details;

2) information on a person, in whose name the registration certificate for a medical device can be issued;

3) address of origin (manufacture) of the medical device;

4) name of the medical device, if its properties and characteristics affecting the quality, efficiency and safety of the medical device stay unchanged, or its properties and characteristics have been improved while the functional purpose and(or) the principle of operation stay unchanged;

5) change of the validity term of documents contained in the registration dossier by manufacturer of the medical device;

6) information on the authorised representative of the manufacturer of the medical device.

Changes in the technical documentation of the manufacturer for the medical device, the operating documentation of the manufacturer for the medical device, including the instruction for use or operation manual for the medical device (except for changes in the name of the medical device) shall be subject to the expert appraisal of quality, efficiency and safety of the medical device conducted in the procedure similar to the procedure for conducting such expert appraisal for the purposes of its state registration if the registering authority based on the verification of the documents submitted determines that the respective changes may entail a change in the properties and characteristics affecting the quality, efficiency and safety of the medical device, or improves its properties and characteristics while the functional purpose and(or) the principle of operation stay unchanged.

An exhaustive list of documents is established for making changes to the documents contained in the registration dossier.

The following timing is provided for the registering authority to make changes to the documents contained in the registration dossier (from the date of the decision to consider the application for making changes and necessary documents):

- 15 business days where the changes do not require the expert appraisal of quality, efficiency and safety of the medical device;

- 35 business days where the changes require the expert appraisal of quality, efficiency and safety control of the medical device.

5. Refusal in and Cancellation of the State Registration

An additional ground for refusal in state registration of a medical device is provided for: detection by the registering authority based on the results of state control over the medical devices circulation of inconsistencies in data on efficiency and safety of the medical device with data on the medical device contained in the registration application and documents submitted.

The following additional grounds were also established for the decision of the registering authority to cancel the state registration of a medical device:

- detection according to the results of state control over the medical devices circulation of unreliable data in the documents contained in the registration dossier submitted by the applicant and affecting the quality, efficiency and safety control for the medical device;

- receipt by the registering authority of the opinions of the expert institution that the device, apparatus, instrument, equipment, material and other items contained in the state register are not suitable for medical purposes and are not medical devices in their function and/or principle of operation.

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The relevant changes to the Registration Rules became effective on 13 June 2018.

Please note that during the transition period until 31 December 2021:

- registration of a medical device at the choice of the manufacturer (its authorised representative) can be performed in accordance with the Rules of Registration and Safety, Quality and Efficiency Control approved by the Decision of the Council of the Eurasian Economic Commission No. 46, dated 12 February 2016, or in accordance with the legislation of the EAEU member-state;

- medical devices registered in accordance with the legislation of the EAEU member-state can circulate in the territory of that state only;

- documents confirming the registration of medical devices and issued by the competent authority the EAEU member-state in the area of public health in accordance with the legislation of that state shall be valid until the end of their validity, but not later than 31 December 2021.

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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

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What we do:

- advising on the requirements and restriction regarding the import and circulation in Russia and other states of medicines and medical products;

- advising on and legal support for participation in public procurement, including representation in appealing decisions and actions of clients;

- advising on legal compliance of advertising and marketing materials and activities, marking, packing, and labels;

- representing interests in the course of public discussions of the drafts of regulatory legal acts including acts of Eurasian Economic Commission.

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