GRATA INTERNATIONAL

SIMPLIFICATION OF THE PROCEDURE FOR STATE REGISTRATION OF MEDICINES IN RUSSIA

On 17 May 2018, amendments to the Federal Law 'On the Circulation of Medicines' (hereinafter - the 'Draft Law'), which simplify the procedure for registration of medicinal products for foreign manufacturers of medicines, were adopted in the third final reading.

According to the amendments are aimed to shorten the terms for accessing by medicines the Russian market and to promote the development of contract manufacturing of medicines in Russia by allowing Russian manufacturers to manufacture on contractual basis medicines developed by other manufacturers.

The Draft Law provisions are in line with the provisions of the Treaty on the Eurasian Economic Union dated 29 May 2014, the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union dated 23 December 2014, and are harmonised with the provisions of the Rules for Registration and Examination of Medicines for Medical Use approved by the Decision of the Council of the Eurasian Economic Commission No. 78 dated 3 November 2016.

State Registration of Medicinal Products and Amending the Registration Files

It is clarified that the state registration of one medicinal product filed for the state registration with respect to the same holder of the registration certificate of a medicinal product in the form of two or more medicinal products under different trade names is not allowed. This amendment, according to the explanatory note to the Draft Law, will allow registering medicines with similar international non-proprietary name, but with different trade names, manufactured on the same production site.

Thereat, in case of state registration of the same medicinal product as two or more medicinal products under different trade names, the competent federal executive authority (hereinafter - the 'competent authority') may cancel the state registration of the medicinal product and exclude it from the state register of medicines.

It is established that if a medicinal product is manufactured outside the Russian Federation and a foreign manufacturer of the medicinal product does not posses the statement on the manufacturer's conformity with the good manufacturing practice rules, issued by the competent authority, the foreign manufacturer may submit a copy of the decision of the competent authority on the inspection of the foreign manufacturer, included in:

- the registration file for state registration of the medicinal product; and
- documents required to confirm the registration of the medicinal product and amending the registration file.

To conduct the quality inspection with respect to a pharmaceutical substance intended for sale in order to include it into the state register of medicinal products, where the medicinal product is manufactured outside of Russia, it will also be necessary to provide a copy of the statement on the manufacturer's conformity with the good manufacturing practice rules, issued by the competent authority, or a copy of the decision by the competent authority to conduct an inspection of the manufacturer, in addition to a copy of the document issued by the competent authority of the manufacturer's country that confirms the authorisation of the medicinal product manufacturing.

With respect to biological medicinal products for medical use, the applicant will be additionally required to submit the results of measures provided for by the risk management plan approved by the competent authority.

The application for confirmation of the state registration of a medicinal product for veterinary use shall be filed with the documents containing the results of monitoring the efficacy and safety of the medicinal product carried out by the holder of the registration certificate of the medicinal product or by an authorised legal entity, in the form approved by the competent authority.

Submission of a copy of the document that confirms payment of the state fee along with the application for confirmation of the state registration of a medicinal product will cease to be obligatory.

Amendments also establish the time limits for taking a decision on amending or refusal to amend the documents contained in the registration file on a registered medicinal product for medical use or veterinary use:

- up to 90 business days in the event it is necessary to conduct the quality examination of medicines and/or examination of the ratio of expected benefit to possible risk of the medicine's use,
- in other cases - up to 30 business days from the date of acceptance of the relevant application by the competent authority.

Suspension of a Medicinal Product Use

It is provided that the competent authority shall consider the suspension of the use of medicinal products for medical use when it receives information on the manufacturer's non-compliance with the rules of good manufacturing practice and(or) on violation of licensing requirements identified during the inspection of the manufacturer or licensing control in the area of medicines manufacturing, which led or may lead to manufacturing of medicinal products for medical use that caused or is likely to cause harm to the life or health of citizens, in the following cases:

1) the composition and(or) technology of manufacturing of a medicinal product for medical use (with the description of manufacturing stages) differ from those stated in the registration files;
2) the medicinal product for medical use has been manufactured at a production site not specified in the registration files;
3) the manufacturer of medicinal products does not have documents confirming the conformity of quality of the medicinal product for medical use that is being introduced in circulation with the requirements established at its state registration;
4) the manufacturer of medicinal products within the term agreed with the relevant competent authority failed to eliminate violations of the requirements of the rules of good manufacturing practices and(or) licensing requirements that were identified during the inspection of the manufacturer or licensing control in the production of medicinal products and that led or may lead to the manufacturing of medicinal products for medical use that caused or is likely to cause harm to the life or health of citizens.

Similar provisions are provided for the suspension of the sale and use of medicinal products for veterinary use.

The amendments will come into force after the Draft Law is approved by the Council of Federation, signed by the President of Russian Federation and the Federal Law is officially published.

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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 restrictions regarding the import and circulation in Russia and other states of medicines and medical devices;
- advising and legal support in participating in public procurement;
- advising on legal compliance of advertising and marketing materials and activities, marking, packing, and labels of commodities;
- representing clients' interests in the course of public discussions of the drafts of regulatory legal acts, including acts of Eurasian Economic Commission.

Contacts:

Yana Dianova
Director of the Corporate and Commercial Law Department
GRATA International (Moscow)
Tel: +7 (495) 660 11 84
E-mail: ydianova@gratanet.com