GRATA INTERNATIONAL

MARKING AND MONITORING OF MEDICINES CIRCULATION IN RUSSIA FROM 2020

Pursuant to the changes in the Federal Law 'On Circulation of Medicines' introduced by Federal Law No. 425-FZ, dated 28 December 2017 ('Law No. 425-FZ'), from 1 January 2020 the federal state information system for monitoring the circulation of medicines for medical use from the manufacturer to the end user with the application of identification marks (system for monitoring the medicines circulation) will start functioning in Russia.

Legal entities and individual businessmen engaged in the production, storage, import, release, sale, transfer, use, and destruction of medicines will have to ensure that information on the medicines is entered in the system for monitoring the medicines circulation.

The information contained in the system for monitoring the medicines circulation will be placed on the Internet (including in the form of open data).

Manufacturers of medicines will be required to place on primary packaging (if no secondary packaging is provided for the relevant medicines) and secondary (consumer) packaging of medicines for the medical use the identification marks. An exception is provided for the medicines for medical use that are:

- produced for clinical trials, export;
- not subject to state registration;
- intended for use in the conditions of military operations, emergency situations, prevention and treatment of diseases caused by the adverse chemical, biological, radiation factors, and developed on the instructions of the federal executive authorities in the area of national defense and state security.

The procedures for marking medicines for medical use, for creating and operating a system for monitoring the medicines circulation and for providing information contained in this system will be established by the Government of the Russian Federation.

The manufacturing or sale of medicines for medical use without the identification marks, in violation of the established procedure for such marking, as well as the late entry of data or entry of false information into the system for monitoring the medicines circulation shall involve the liability for legal entities and individual businessmen in accordance with legislation[1].

In addition to the changes listed above, the Federal Law 'On Circulation of Medicines' is supplemented with provisions that the state register of medicines will include:

- information on the registration of the holder or owner of the registration certificate of the medicine for medical use as a taxpayer in the country of registration[2];
- name and address of the manufacturer of the medicine and information on the registration of the manufacturer of the medicine for medical use as a taxpayer in the country of registration.

[1] In particular, violations in marking medicines may involve administrative liability for the manufacturers in accordance with Article 15.12.1 of the Administrative Code.

[2] For Russian legal entities - identification taxpayer's number (INN), for foreign legal entities - the country of registration, name of the registering authority, registration number, taxpayer's code in the country of registration (incorporation) or equivalent).

The information on the holder of the registration certificate of the medicine listed above will also be included in the state register of the manufacturer's maximum selling prices for medicines contained in the list of vital and essential medicines.

With respect to pharmaceutical substances produced for sale, the state register of medicines will include: name, address of the manufacturer of the pharmaceutical substance, and in respect of the medicine for medical use - information on the registration of the manufacturer of a pharmaceutical substance as a taxpayer in the country of registration.

Until 1 January 2019 holders of the registration certificates of the medicines and manufacturers of medicines for medical use registered before the entry into force of Law No. 425-FZ and manufacturers of pharmaceutical substances included into the state register of medicines for medical use before the entry into force of Law No. 425-FZ shall submit to the competent authority the information on their registration as taxpayers in the country of registration.

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Best Regards,

GRATA International Law Firm (Moscow)

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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 and legal support in participating in public procurement;
- 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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