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CHANGES IN THE RULES OF SUBSIDISING THE CLINICAL TRIALS OF IMPLANTABLE MEDICAL DEVICES IN RUSSIA

The Decree of the Government of the Russian Federation No. 37 dated 20 January 2017 amended the Rules for Granting Subsidies from the Federal Budget to Russian Organisations for Partial Compensation of Costs Incurred for the Implementation of Projects on the Arrangement and Conducting of Clinical Trials of Implantable Medical Devices within the Sub-Program 'Development of the Medical Devices Production'' of under the State Program 'Development of the Pharmaceutical and Medical Industry' for 2013-2020 (hereinafter - the "**Rules**") approved by the Decree No. 1046 of the Government dated 1 October 2015.

The changes are aimed at enhancing the incentives to Russian manufacturers for the development of implantable medical devices and accelerating their market launch.

The list of works, for which the subsidies are available, is expanded: such works are now include scientific research, design and developments, and technological works, arrangements and conducting of clinical trials of medical devices. (Under the previous version of the Rules, subsidies were only granted for the projects for arrangements and conducting of clinical trials of medical devices.)

The Rules also provide for subsidising experts' salaries, design and development, as well as technological works, manufacturing models and experimental lots of medical devices.

The amount of the subsidised costs was increased from 50 to 80% of actual costs, the maximum amount of subsidies - from 5 million roubles to 200 million roubles - in order to optimise the reimbursement of actual costs being sustained by of medical devices manufacturers to perform the relevant works.

The frequency of granting of the subsidies was also changed - now it is a monthly basis rather than every six months, which will allow manufacturers of medical devices to apply for subsidies for partial reimbursement of their costs incurred in any month.

At the same time, the requirements for the content of the business plan submitted by an entity when applying for subsidies were expanded, including in terms of the justification of demand for medical devices, performance indicators as of the end of each half year, information on the structure of the relevant costs.

The list of performance indicators of the project implementation now includes new indicators: in particular, the sales volume of medical devices, share of newly developed medical devices in the total volume of output, number of new and upgraded high-tech jobs.

The relevant changes to the Rules became effective on 30 January 2017.

The federal budget for 2017 provides for 705.9 million roubles for granting the subsidies for the development and clinical trials of implantable medical devices.

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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 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;
- 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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