Significant changes made to circulation procedure for medical devices

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On 11 May 2021, a law* came into force, which changes and supplements the rules for the circulation of medical devices.

The main changes are as follows:

- The production of medical devices will no longer require a licence. Licensing is being replaced with a quality management system.
- The list of medical devices that are not subject to state registration has been expanded.
- Clear rules have been established for the circulation of medical devices in case of termination of their registration certificate or amendments to their registration documentation.
- The concept of a "defective medical device" has been changed.
- The procedure for monitoring the safety of medical devices has been adjusted.

The new rules eliminate gaps and uncertainties in the current legislation, which reduces the risks of market participants and makes the legislation on the circulation of medical devices more comprehensive and transparent. However, implementing the new rules could require companies active in the Russian market to change their internal processes, which will take both time and money.

Replacement of production licensing with a quality management system

From 1 January 2022, the licensing of the production of medical devices will be cancelled. Instead, medical device production must comply with the requirements for the implementation, maintenance and evaluation of a quality management system for medical devices, which will depend on the potential risk for their use.

The Russian government will set these requirements, as well as the procedure for organising and conducting inspections for compliance with such requirements, including the methodology for calculating fees for inspections.

At the same time, market participants are required to get their licences for the production and maintenance of medical equipment transformed into the corresponding maintenance licences by 1 January 2024. The licensing authorities will carry out these formalities without additional verifications, except for cases when changes are made to the list of works performed under a given licence.

Medical devices relieved from state registration

The new rules clarify and expand the list of medical devices that do not require state registration. As a result, medical devices will no longer be subject to state registration when they are:

- manufactured in Russia and intended for export from the Eurasian Economic Union (EAEU) or for development work, research or testing;
- imported into Russia for the provision of medical care according to the vital indications of a particular patient;
- composed of packs, kits and first-aid kits combined by common packaging and these packs, etc. consist of registered medical devices (except for electrical medical devices) and/or medical products, provided that the packaging and labelling of such devices and products are preserved;
- intended for in vitro diagnostics, if they are manufactured and used in a medical organisation, provided that this organisation obtains permission from Roszdravnadzor for such activities (from 1 January 2022).

The Russian government will establish the procedure for importing medical devices into Russia that are not subject to registration.

Circulation of medical devices after the expiration of a registration certificate

The new law establishes clear rules for the circulation of medical devices after their registration period expires or after the registration documentation has been amended. The previous legislation did not clearly regulate this issue, and the regulatory authorities expressed their position to market participants in individual letters, which were often contradictory.

According to the amendments, at the end of the validity period of a registration certificate and until the end of the service life or shelf life of a medical device, the operation and use of such device is permitted, including carrying out maintenance, transportation, installation, tuning, adjustment and calibration of the device, as well carrying out other operations required for its commissioning. However, it is prohibited to take other actions with medical devices whose registration has been terminated, including production and sale.

Similar to medicines, a transitional period has been established for the circulation of medical devices after the introduction of changes in their registration documentation. The new rules stipulate that medical devices manufactured in accordance with the previously valid registration dossier before the date of the changes, as well as within 180 calendar days after such changes, can freely circulate on the market.

Defective medical devices

The new law expands the criteria for declaring a medical device defective. A product will now be recognised as defective if:

- it does not meet requirements in terms of:

  — safety and efficacy of medical devices;
  — labelling;
  — regulatory, technical and operational documentation; and

- at the same time, it cannot be safely used for the intended purpose established by the manufacturer.

This definition is clearer and less formal than the previous one. Now, to recognise a medical device as defective, mere formal non-compliance with the requirements is not sufficient. One must prove that the revealed non-conformity negatively affects the safety of the medical device.

It is too early to definitively assess how significantly this change will affect the law enforcement practices of Roszdravnadzor when identifying defective medical devices.

Monitoring the safety of medical devices

The changes also affect the procedure for monitoring the safety of medical devices in order to identify and prevent adverse events. Thus, when monitoring, attention will be paid to the classification of adverse events, which Roszdravnadzor will have to subsequently approve. Safety monitoring should be carried out at all stages of the circulation of a medical device both in Russia and on the territory of other countries. Among other things, information that the medical device manufacturer, its authorised representative or the importer submits to Roszdravnadzor will be analysed as part of the monitoring.

Roszdravnadzor is expected to approve a procedure for monitoring the safety of medical devices (except for those registered in accordance with the rules of the EAEU), reflecting the changes that have come into force.

If you have any questions on this eAlert, do not hesitate to contact CMS Russia experts **Vsevolod Tyupa**, **Alexey Shadrin** or your regular contact at CMS Russia.

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** In Russian*

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