ADMINISTRATIVE LIABILITY FOR THE VIOLATIONS IN THE AREA OF CIRCULATION OF MEDICINES, MEDICAL DEVICES AND BIOLOGICALLY ACTIVE SUPPLEMENTS IN RUSSIA
The Federal Law No. 532-FZ (the 'Law No 532-FZ'), which entered into force on 23 January 2015, introduced significant changes in terms of liability for the circulation of medicines, medical devices and biologically active supplements (BAS) that do not meet the statutory requirements. Firstly, the Federal Law No. 323-FZ dated 21 November 2011 'On the Fundamentals of Public Health Protection in the Russian Federation' (the 'Law No. 323-FZ') was supplemented with definitions of 'falsified', 'counterfeit', 'poor-quality' and 'unregistered' medical devices, and the Federal Law, dated 2 February 2000, No. 29-FZ 'On Quality and Safety of Food Products' - with a definition of falsified BAS. Secondly, the amendments increased measures of administrative liability for circulation of falsified, counterfeit, poor-quality and unregistered medicines, medical devices and falsified BAS. Thirdly, criminal liability was introduced for the manufacturing of medicines or medical devices without a special permit (license)\(^1\), for the manufacturing, sale or import into Russia of falsified or unregistered medicines or medical devices, as well as falsified BAS and some other acts\(^2\).

In this article we review practical aspects of application of the provisions on administrative liability introduced by the Law No. 532-FZ, as well as previously existing provisions of the Code of Administrative Violations of the Russian Federation (the Administrative Code) regarding circulation of medical devices.

**Violations of the Rules in the Area of Medical Devices Circulation**

Violations of the rules established in respect of medical devices circulation, if they do not contain the signs of a criminal offense, shall entail an administrative fine: on citizens in the amount of up to 4,000 roubles; on officials - up to 10,000 roubles; on legal entities - up to 50,000 roubles (in accordance with Article 6.28 of the Administrative Code introduced by the Federal Law No. 317-FZ dated 25 November 2013).

Circulation of medical devices, pursuant to Article 38 of the Law No. 323-FZ, shall include technical testing, toxicological studies, clinical trials, assessment of quality, effectiveness and safety of the medical devices, state registration, production, manufacturing, import into and export from the territory of Russia, confirmation of conformity, state control, storage, transportation, sale, installation, commissioning, application, operation, including maintenance as provided by the regulatory, technical and(or) operational documentation of the manufacturer (producer), as well as repairs, recycling or destruction.

As a general rule, in the territory of Russia medical devices shall be allowed for circulation subject to the registration with the Federal Service for Supervision in the Area of Health Care (Roszdravnadzor) according to the procedure specified by the Government of Russia.

Thereat, the following medical devices shall be prohibited for manufacturing:

- medical devices not included in the state register of medical devices and organisations (individual businessmen) engaged in the production and manufacture of medical devices, except for medical devices manufactured for trials and(or) research;
- **falsified medical devices** (i.e. those accompanied with false information on their characteristics and(or) manufacturer).

---

\(^1\) Article 235.1 of the Criminal Code;  
\(^2\) Article 238.1 and Article 327.2 of the Criminal Code
Besides, import into and sale in the territory of Russia is prohibited for falsified medical devices, poor-quality medical devices (i.e. those not complied with the requirements of regulatory, technical and (or) operational documentation of the manufacturer, or other regulatory documents), and counterfeit medical devices (i.e. those being in circulation with violation of civil laws, mainly in the area of intellectual property rights – in particular, with the use of trademarks without permission of the respective trademarks' owner).

Cases on administrative violation provided by Article 6.28 of the Administrative Code are considered by the Federal Service for Supervision in the Area of Health Care (Roszdravnadzor) and its territorial bodies.

According to the case law, the liability provided by Article 6.28 of the Administrative Code is imposed, inter alia, for:

- the use of medical devices that are not registered according to the established procedure, including if a person who uses the device has initially believed that the device is not intended for medical use;
- the use of medical devices with expired shelf life and in violation of storage conditions.

Moreover, before the introduction of a special liability for circulation of counterfeit medical devices, the administrative fines, pursuant to Article 6.28 of the Administrative Code, were imposed for the supply of medical devices the labels on the packaging of which contained false information on the medical device and its manufacturer, and in the absence of proper registration certificate for the medical devices.

The courts usually refuse in satisfaction of the violators' claims for cancellation of decisions on bringing them to administrative liability for violation of the rules in the area of medical devices circulation generally based on Article 2.1. p. 2 of the Administrative Code under which a legal entity shall be held liable for committing an administrative violation if it is established that the legal entity could comply with the rules and regulations, violation of which entails administrative liability under the Administrative Code or other laws, but failed to take all reasonable measures to comply with such rules and regulations.

Thereat, according to the explanations of the Plenum of the Supreme Arbitration Court of the Russian Federation (SAC), in respect of legal entities it is only required to establish that the relevant entity had the opportunity to comply with the rules and regulations, the violation of which entails an administrative liability, but failed to take all reasonable compliance actions.

The courts also disregard the argument of liable entities that the violation may be considered insignificant, since their actions do not constitute a threat of harm to human health and life, if

---

3 The Resolution of the Fourteenth Arbitration Appellate Court dated 22 September 2014 on the case No. A05-5444/2014;  
5 The Resolution of the Nineteenth Arbitration Appellate Court dated 2 December 2015 No. 19APII-5399/2015 on the case No. A08-3683/2015;  
7 Clause 16.1 of the Resolution of the SAC Plenum No. 10, dated 2 June 2004;
there are no any exceptional circumstances that allow to apply Article 2.9 of the Administrative Code which provides for the possibility of release from administrative liability in case of insignificance of the administrative violation.

In this case, the courts rely on the decision of the Constitutional Court of the Russian Federation No. 11-P dated 15 July 1999 under which the sanction must meet the requirements of fairness and proportionality. The principle of proportionality implies that public liability may be imposed for a violation at fault only and liability may be differentiated depending on the severity of the violation, amount and nature of the damage, degree of the violator's guilt and other material circumstances, which determine the individualization of punishment application.

At the same time, the courts annul decisions of Roszdravnadzor on administrative liability, if in the course of the case consideration they establish that this controlling authority committed a material breach of the procedure established by the Administrative Code, in particular⁸:

- an administrative case was considered in the absence of a person against whom the proceedings were conducted (in violation of Article 25.1 of the Administrative Code.);

- an administrative violation protocol does not comply with the requirements established by Article 28.2 of the Administrative Code, the controlling authority inaccurately executed the procedural documents which are the main evidence in bringing persons to administrative liability (in violation of Articles 26.2, 28.1, 28.2 of the Administrative Code).

The material nature of breaches on the part of Roszdravnadzor is determined by based on the effects of the violation and the possibility of eliminating such effects. In particular, a failure to ensure that a person being brought to administrative liability may exercise its rights for protection of its interests in the course of administrative proceedings is deemed a material breach.

**Circulation of Falsified, Counterfeit, Poor-quality and Unregistered Medicines, Medical Devices and Falsified BAS**

The Law No. 532-FЗ supplemented the Administrative Code with Article 6.33, which establishes administrative liability for the following violations:

- manufacturing, sale or import into the territory of the Russia of falsified medicines or medical devices;

- sale or import into the territory of the Russia of counterfeit medicines or medical devices, or circulation of falsified BAS, if such actions do not contain the signs of a criminal offense;

---

⁸ The Resolution of the Sixteenth Arbitration Appellate Court dated 27 August 2015 No. 16АП-2861/2015 on the case No. A20-1304/2015;
sale or import into the territory of the Russia of poor-quality medicines or medical devices, or illegal manufacturing, sale or import into the territory of Russia of unregistered medicines, if such actions do not contain the signs of a criminal offense; an administrative fine is imposed on citizens in the amount of up to 100 thousand roubles; on officials - up to 600 thousand roubles; on individual businessmen - up to 600 thousand roubles or an administrative suspension of activity for up to 90 days; on legal entities - up to 5 million roubles or an administrative suspension of activity for up to 90 days.

Administrative cases in connection with violation under Article 6.33 of the Administrative Code are considered by the judges. Depending on the type of a violation specified by Article 6.33 of the Administrative Code, a protocol on administrative violation (on the basis of which a case is considered) may be issued by:

- customs officials;
- officials of the authorities engaged in the control and supervision in the area of healthcare;
- officials of the authorities engaged in the federal state sanitary and epidemiological supervision (in terms of circulation of falsified BAS);
- officials of the authorities engaged in the federal state supervision in the area of customers' rights protection.

The practice of bringing to liability for violations specified by Article 6.33 of the Administrative Code, is quite extensive and includes the following cases:

1. retail sale by a pharmacy organisation of a poor-quality medicine, which does not meet the quality standard provided by the certified pharmacopeial description of the manufacturer. The court reasoned its decision to impose an administrative fine in the amount of 500,000 roubles by the fact that the pharmacy organisation engaged in the business in the area of medicines circulation was obliged to monitor the quality of sold medicines, take all possible measures to prevent the sale of poor-quality medicines, including conducting expert appraisal thereof both by its own and by contracted persons and approaching in a responsible way to the choice of suppliers, which was not done by the organisation in this case;

2. wholesale by a pharma distributor of falsified medicine accompanied with false information on its characteristics and(or) manufacturer. Since CV Protek Company ZAO, possessing a license for pharmaceutical activities (wholesale) and being a large distributor of pharmaceutical products in 28 regions of Russia, was obliged and had the opportunity to verify the compliance of the sold product with the original packaging of the manufacturer and identify the differences, but nevertheless sold falsified medicines, it was sanctioned with an administrative fine in the amount of 1 million roubles. Thereat, the court did not accept the company's argument that it did not have technical capacity to test medicines for authenticity, stating that the company should arrange a system of internal control to prevent the entry of falsified medicines into circulation through taking a set of measures: selection of bona fide suppliers,

---

selection and constant monitoring of personnel to avoid any possibility of "smuggled' goods, etc.  

3. sale by an individual businessman of medicines that, according to information provided to consumers, are actually medicines by the methods of use (injection) and effect on a human body, but were not registered according to the established procedure. The businessman, in this case, was sanctioned with an administrative fine in the amount of 100,000 roubles  

4. supply to a medical institution medical devices the labels of which contained false information in the devices' appellations, models (versions) and the name of the manufacturer and did not comply with the accompanying documents and the registration certificate. Despite the fact that the supplier provided an expert opinion on the biological safety of the medical device, the court concluded that the device was not safe, since it established the signs of the device falsification, and the supplier was brought to administrative liability in the form of a fine in the amount of 500,000 roubles. 

At that, the fact that a medicine which should have been withdrawn from circulation and returned to the supplier (manufacturer) according the letters of Roszdravnadzor due to a mismatch to the requirements of regulatory documents was stored in a pharmacy's material cabinet together with other medicines, as well as the storage of a medicine with expired shelf life in a fridge outside of the quarantine zone was deemed by the court as an administrative violation that entails liability provided for by Article 14.43 p. 1, rather than Article 6.33 of the Administrative Code.

At the same time, Russian courts refused to impose administrative liability in the following cases:

1. the sale of BAS that do not meet the requirements of the Technical Regulations of the Customs Union 'On Safety of Food Products' (TR TS 021/2011) was not recognised as circulation of falsified food additives provided that the respective businessman or organisation took all reasonable and adequate measures to confirm the legality of the sold BAS, in particular, they obtained the relevant declarations of

---

14 A violation by the manufacturer, contractor (a person performing the functions of a foreign manufacturer), seller of the technical regulations or obligatory requirements to products and related processes of design (including survey), manufacturing, construction, installation, commissioning, operation, storage, transportation, sale and utilization or release into circulation of products not conforming to these requirements, which are to be applied before the entry into force of the said technical regulations.  
conformity (quality declaration), conformity certificated from the supplier (manufacturer)\textsuperscript{16};

2. in the course of seizing samples of poor-quality medicines and drafting a protocol administrative violation, the territorial divisions of Roszdravnadzor violated the requirements of the Administrative Code\textsuperscript{17};

3. the territorial division of Roszdravnadzor did not provide documentary evidence that composition of the sold product included components that have a therapeutic effect, and, accordingly, it is a medicine that is subject to state registration\textsuperscript{18}.

****

Based on the judicial practice on cases of bringing to administrative liability for violations in the area of circulation of medicines, medical devices and BAS, we can make the following conclusions.

1. Although Article 6.33 of the Administrative Code that provides for administrative liability for circulation of falsified, counterfeit, poor-quality and unregistered medicines, medical devices and circulation of falsified BAS was introduced relatively recently, the territorial divisions of Roszdravnadzor quite actively initiate cases on administrative violations based on this article and the courts generally impose fines in large amounts (from 500 thousand up to 1 million roubles) on the wrongdoers.

2. The courts' approach to the criteria for determining objectiveness of administrative violations varies depending on whether it is about falsified, counterfeit, poor-quality medicines, or falsified BAS. In the first case, the courts presume that professional subjects of medicines circulation, including pharmacy organisations and pharmaceutical distributors, shall take all possible measures to prevent the sale of poor-quality and falsified medicines, including through the appropriate testing and selecting bona fide suppliers. In case of sale of falsified BAS, in order to avoid liability, it is sufficient for a businessman or an organisation to prove that they have documents confirming BAS conformity (i.e. certificates of the registration) and they are not required to conduct BAS quality testing by their own.

3. The courts refused to impose administrative liability, if the territorial divisions of Roszdravnadzor committed material breaches of the procedural requirements established by the Administrative Code in the course of inspections of respective individual businessmen and organisations. In this regard, it is important to ensure qualified legal support both in the course of the relevant inspections and subsequently in challenging the decisions of the courts and controlling authorities on bringing to administrative liability.

\textsuperscript{16} The Resolution of the Thirteenth Arbitration Appellate Court dated 1 August 2016 No. 13АП-13191/2016 on the case No. A56-351/2016;

\textsuperscript{17} The Resolution of the Thirteenth Arbitration Appellate Court dated 23 June 2016 No. 13АП-10571/2016 on the case No. A21-9765/2015;

\textsuperscript{18} The Resolution of the Fourth Arbitration Appellate Court dated 23 March 2016 No. 04АП-332/2016 on the case No. A19-17390/2015;
Best Regards,

GRATA International Law Firm (Moscow)

This information is provided for your convenience and does not constitute legal advice. It is prepared on the basis of laws and courts decisions effective as of August 2016 for the general information of our clients and other interested persons and it may include links to websites other than the GRATA International website. This information should not be acted upon in any specific situation without appropriate legal advice.

What we do:

- Advising on the statutory requirements and restrictions regarding the import and circulation of medicines, medical devices and foods supplements in the Russian Federation, and participation in state procurements;
- Representing before Roszdravnadzor, other controlling authorities and in courts;
- Development/review of distribution agreements, supply contracts, agent agreements, contract agreements, services and other contracts;
- Development/review of the procedure for selection of counter-parties, commercial/trade policies, in view of the requirements of antitrust and tax authorities;
- Advising on legal compliance of advertising and marketing materials and activities;
- Support of the inclusion of trademarks and other intellectual property objects into the Unified Register of Intellectual Property Objects;
- Representing in disputes with counter-parties and those related to the consumers’ claims.

Contacts:

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