OVERVIEW OF LEGISLATIVE DEVELOPMENTS IN MEDICINES' AND MEDICAL DEVICES’ CIRCULATION DOMAINS
I. Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union

The Agreement on Uniform Principles and Rules for the Medicines’ Circulation within the Eurasian Economic Union signed on 23 December 2014 by the member states of the Eurasian Economic Union (hereinafter - the "EEU") provides for commitments of Russia, Kazakhstan and Belarus in connection with formation of the common market of medicines that meet the requirements of good pharmaceutical practices in accordance with Article 30 of the EEU Treaty, dated 29 May 2014, and for the measures to be taken to implement by the member states coordinated policies in the domain of medicines’ circulation.

The state pharmacopoeia’s of the member states will be harmonised on the basis of international experience in harmonisation of national pharmacopoeia requirements in accordance with the concept approved by the EEU Committee (hereinafter - the “Committee”). Pharmacopoeia norms and regulations (public and private) in aggregate will form the EEU Pharmacopoeia to be approved by the EEU Committee.

Preclinical and clinical trials of medicines in the member states will be carried out in accordance with the rules of good laboratory practice, good clinical practice and requirements for trials of medicines to be approved by the Committee.

Registration and examination of medicines manufactured for circulation in the common market of medicines within the EEU will be carried out by the member states in accordance with the rules for registration and examination of medicines based on the list of dosage forms approved by the Committee. Medicines registered in the member states in accordance with these rules will not be subject to re-registration in accordance with national laws.

The member states shall mutually recognise the results of pre-clinical (non-clinical), clinical and other trials (tests) of medicines, the results of the inspection of manufacturing, pre-clinical (non-clinical), clinical trials (tests) of medicines, pharmacovigilance systems performed in compliance with the rules of good pharmacy practice and requirements approved by the Committee.

Any disputes arising in the course of the registration of medicines shall be settled by the Expert Committee on Medicines formed by the Committee.

Medicines will be allowed for sale within the EEU subject to their registration in accordance with the procedure established by the Committee and inclusion in the EEU unified register of registered medicines.

Manufacturing of medicines within the EEU will be carried out in accordance with the rules for good manufacturing practice to be approved by the Committee and on the basis of a permit (license) for manufacturing of medicines issued in accordance with the laws of the member states.

The wholesale, transportation and storage of medicines in the territories of the member states will be carried out in accordance with the rules for good distribution practices approved by the Committee.

The authorised bodies of the member states will control over the observance by the holders of medicines’ registration certificates of pharmacovigilance obligations in accordance with good pharmacovigilance practice approved by the Committee, and the laws of the member states.

The authorised bodies of the member states will interact as well to identify falsified and (or) counterfeit medicines according to the procedure approved by the Committee.

The Committee will form and maintain on the basis of information submitted by the authorised bodies of the member states:

- the EEU unified register of registered medicines with the information databases on instructions for medical use, packages graphic designs and quality normative documents;
- the unified information database of medicines that do not meet quality requirements, as well as falsified and (or) counterfeit medicines identified in the territories of the member states;
− the unified database of information on the identified adverse effects of medicines, including notifications on ineffectiveness of medicines;
− the unified information database on suspended, withdrawn and banned medicines.

The Committee will also establish and provide for operation of the EEU information system on medicines with the information on the requirements to medicines circulation applicable in the EEU, information contained in the unified register and information databases, as well as pharmacovigilance data and other information.

The Agreement will enter into force on the date of receipt by the depositary of the last written notice of the fulfilment by the member states of internal procedures required there for, but not earlier than 1 January 2016.

Medicines registered in the members states prior to the entry into force of the Agreement should be brought in compliance with the EEU requirements and rules until 31 December 2025 according to the procedure established by the rules of registration and examination of medicines approved by the Committee.

Until the entry into force of the rules of good laboratory practice, good clinical practice and other rules and regulations to be approved by the Committee governing the medicines circulation, the national laws of the member states will apply.

II. Agreement on Uniform Principles and Rules for the Circulation of Medicines (medical devices and equipment) within the Eurasian Economic Union

The Agreement on the Uniform Principles and Rules for the Circulation of Medical Devices within the Eurasian Economic Union, signed on 23 December 2014, provides for the obligations for the EEU member states to develop a common market of medical devices within the EEU in accordance with Article 31 of the EEU Treaty dated 29 May 2014, and to implement a coordinated policy in the domain of circulation of medical devices.

Registration of medical devices to be released for circulation within the EEU will be performed by the authorised bodies of the member states according to the procedure to be approved by the Committee.

Examination of safety, quality and efficacy of medical devices for the purpose of their registration will be carried out by an expert organisation determined by the state authority of the member-state in the domain of healthcare according to the procedure to be approved by the Committee.

The Committee will approve as well:
− the rules for classification of medical devices depending on the potential risk of application,
− the rules for keeping medical devices lists (nomenclatures);
− general requirements to safety and effectiveness of medical devices, as well as to operational documentation for medical devices;
− the rules for trials (tests) of medical devices;
− the rules for registration of medical devices (including the requirements for registration dossier, an application for registration, grounds and procedure for suspension or revocation (cancellation) of the registration certificates for a medical device);
− the rules for the examination of safety, quality and efficacy of medical devices;
− the requirements to organisations authorised to conduct trials (testing) of medical devices for the purpose of their registration and the procedure to assess their compliance with these requirements.

The results of trials (tests) and examinations obtained in the course of registration of medical devices shall be mutually recognised by the authorised bodies of member states provided that the respective trials are performed in accordance with the requirements and procedures established by the Committee.
Medical devices will be prohibited for circulation within the EEU, if:

- a) there is a formal notice from the authorised body, manufacturer and(or) representative thereof on suspension of the circulation of a medical device, or withdrawal thereof from circulation, or withdrawal thereof by the manufacturer;
- b) life (shelf life) of a medical device has expired;
- c) a medical device is not duly registered (except for medical devices that are not subject to the registration).

A manufacturer of medical devices designed for circulation in the EEU shall ensure the implementation and maintenance of quality management of medical devices in accordance with the requirements established by the Committee.

A manufacturer will be obliged to submit reports to the authorised bodies based on clinical experience of application of certain types of medical devices with the high potential risk of application. In the event of termination of manufacturing of a medical device, the manufacturer or a representative thereof shall notify the authorised body that issued the registration certificate to the medical device within 30 calendar days from the date of the decision to cease manufacturing.

Medical devices registered and compliant with the unified requirements for safety and efficacy of medical devices and the requirements for implementing and maintaining quality management of medical devices should be marked with a special mark of circulation of the medical device at the EEU market prior to their release in circulation within the EEU.

In the event the circulation of medical devices that pose a threat to human life and (or) health, or defective, falsified or counterfeit medical devices is detected within the EEU, the authorised body within 5 days upon detection of such a fact shall notify thereof the authorised bodies of the other member states and the Committee. The authorised body may also take measures to suspend or prohibit the use of such medical devices or to withdraw them from circulation.

The grounds and procedure for suspension or withdrawal (cancellation) of the registration certificate of a medical device will be determined by the rules of registration of medical devices to be approved by the Committee.

The Committee on the basis of the information submitted by the authorised bodies will form and maintain the information system on medical devices comprising:

- a) the unified register of medical devices registered in the EEU;
- b) the unified register of authorised organisations;
- c) the unified database on the examination of safety, quality and efficacy of medical devices.

The Agreement will enter into force on the date of receipt by the depositary of the last written notice of the fulfilment by the member states of internal procedures required there for, but not earlier than 1 January 2016.

Documents confirming the state registration of medical devices issued by the authorised bodies prior to the entry into force of the Agreement will be effective in the territory of a member state until the expiry thereof, but no later than until 31 December 2021.

III. Changes in the Amounts of State Fees for Registration of Medicines

The Federal Law No. 480-FZ dated 29 December 2014 ‘On the Introduction of Amendments to the part two of Article 333.32.1 of the Tax Code of the Russian Federation’, that comes into force on 1 July 2015, specifies the procedures in connection with the state registration of medicines and sets new amounts of state fees for such registration procedures.

In particular, the state fee for ethical review and examination of documents on a medicine to obtain a permit for a clinical trial will be 110,000 roubles (currently it is 75,000 roubles).

Depending on the need to perform documents examination, the law differentiates fee amounts for amending the documents contained in the registration dossier for the medicine. For instance, the fee for examination of the documents to determine whether a medicine for
medical use qualifies for the purposes of the state registration as an orphan medicine will be 25,000 roubles.

IV. Changes in the Procedure for Selling Narcotic and Psychotropic Medicines


This Law introduced the concepts of 'sale of narcotic drugs, psychotropic substances' and 'delivery of narcotic drugs, psychotropic substances'; the latter includes actions for the transfer of narcotic drugs, psychotropic substances by a legal entity within its organisational structure, as well as to individuals for medical use.

Pharmaceutical organizations, healthcare organisations or separate subdivisions of healthcare organisations located in rural areas and remote areas, where there are no pharmacy organisations, are granted with the right to sell narcotic and psychotropic medicinal products to individuals subject to obtaining the relevant license to conduct such activity.

A list of the relevant healthcare organisations and separate subdivisions thereof as well as the list of narcotic and psychotropic medicines, which may be sold thereby to individuals, will be approved by the executive authorities of the Russian Federation. The list of positions of pharmaceutical and healthcare professionals authorised to sell narcotic and psychotropic medicines to individuals will be approved by the Ministry of Health of the Russian Federation.

Additional requirements to the primary packaging of narcotic drugs and psychotropic substances and shipping container thereof are established: such packages and containers shall exclude the possibility of extracting the contents without breaking them.

It is forbidden to demand the return of primary and secondary packages of narcotic and psychotropic medicines used for medical purposes, i.e. in the form of transdermal therapeutic system containing narcotic drugs, when issuing new prescriptions for narcotic and psychotropic medicinal products.

V. Liability for Trafficking of Falsified, Counterfeit, Defective and Unregistered Medicines, Medical Devices and Counterfeit Dietary Supplements


The Federal Law 'On Fundamentals of Health Protection in the Russian Federation' is supplemented with the concept of 'falsified medical device, 'defective medical device, and 'counterfeit medical device'.

The following are prohibited for manufacturing:

1) 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;

2) falsified medicines.

Falsified medical devices, defective medical devices and counterfeit medical devices are also banned for the import to the territory of Russia and sale therein.

Seized falsified, defective and counterfeit medical devices are subject to destruction according to the procedure to be approved by the Government of the Russian Federation.

Criminal liability is introduced for:

1. manufacturing of medicines or medical devices without a special permit (license), when such a permit (license) is required (obligatory) – in particular, in the form of imprisonment for up to 8 years with a fine of 1 to 3 million roubles or in the amount of a salary or other income for the period from 1 to 3 years or without it (subject to qualifying factors);

2. manufacturing, sale or import into Russia of falsified medicines or medical devices, or sale or import into Russia of defective medicines or medical devices, or illegal manufacture, sale or import into Russia for selling of unregistered medicines or medical
devices, or manufacturing, sale or import into Russia of counterfeit dietary supplements containing pharmaceutical substances not declared at the state registration, performed on a large scale (over 100 thousand roubles);

3. fabrication for use or sale, or use of consciously forged documents on medicines or medical devices (registration certificates, certificate or declaration of conformity, instructions for use, or regulatory, technical and operational documentation of the manufacturer on medical devices), as well as consciously deceptive primary and (or) secondary (consumer) package of the medicinal product.

Furthermore, administrative liability is established for:

1. manufacturing, sale or import into Russia of falsified medicines and medical devices, sale or import into Russia of counterfeit medicines and medical devices, circulation of falsified dietary supplements;

2. sale or import into Russia of defective medicines or sale or import into Russia of defective medical devices, or illegal manufacture, sale or import into Russia of unregistered medicines, -

in the form of a fine on officials - up to 600,000 roubles; individual businessmen - up to 600,000 roubles or administrative suspension of activity for up to 90 days; on legal entities - up to 5 million roubles or administrative suspension of activity for up to 90 days.

The Federal Law 'On Food Quality and Safety' is supplemented with the concept of “falsified foods (including dietary supplements), materials and products”.

Unscheduled site inspections for the purposes of state supervision over compliance with the requirements to quality and safety of foods, materials and products now may be carried out without a prior notice.

VI. New Lists of Medicines for Medical Use

The Order of the Government of the Russian Federation No. 2782-r dated 30 December 2014 approved:

- the list of vital and essential medicines for medical use for the year 2015;
- the list of medicines for medical use, including those prescribed by the decision of medical commissions of medical institutions;
- the list of medicines for treatment of hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignancy of lymphoid, hematopoietic and related tissue, multiple sclerosis, and persons after the transplantation of organs and(or) tissues;
- the minimum assortment of medicines required for medical care.

These lists become effective on 1 March 2015. Prior to that date, the list of vital and essential medicines for the year 2012 (approved by the Order of the Government No. 2199-p dated 7 December 2011) shall apply.

The Ministry of Healthcare of the Russian Federation is mandated to:

- ensure state registration of maximum prices of manufacturers of medicines included in the list of vital and essential medicines for medical use for the year 2015;
- make entries in the state register on the maximum prices of manufacturers of medicines included in the above list, as well as entries on registered prices for such medicines.

VII. List of Medical Devices for Implantation in Human Body and List of Medical Devices Dispensed on Prescriptions

The Order of the Government of the Russian Federation No. 2762-r dated 29 December 2014 approved:

- the list of medical devices being implanted in the human body when providing medical care within the program of state guarantees of free medical care to citizens, containing 204 types of medical devices;
the list of medical devices provided on prescriptions in the course of provision of social services, containing 3 types of medical devices used to control the glucose level in the blood.

VIII. Changes in the Requirements to Sale of Medical Devices

The Decree of the Government of the Russian Federation No. 6 dated 5 January 2015 'On the Introduction of Amendments to the Rules of Sale of Certain Goods', as effective from 20 January 2015, included medical devices in the list of goods prohibited for sale outside of stationary trade points - at home, at the workplace and place of study, on transport, on a street and in other places.

The information on medical devices (instruments, apparatus, appliances, equipment, materials and other products used for medical purposes alone or in combination with each other as well as with other accessories required to apply the above products for the purpose, including special software), being provided to customers, should include the information on the number and date of the registration certificates to the medical devices issued by the Federal Service for Supervision in the Healthcare Area in the prescribed procedure (earlier - 'permit to use'), and, subject to features of a particular type of a medical device, information about its purpose, method and conditions of use, as well as the effect, restrictions (contraindications) for use.

IX. Clarification by the Ministry of Healthcare of the Russian Federation on Classifying Certain Types of Medical Devices as Measuring Tools


According to Ministry of Healthcare, modern digital automatic and automated medical devices with a special proprietary software such as incubators for newborns, analyzers for clinical laboratory diagnostics in vitro, patient monitors, monitors of respiratory functions and respiratory gas anesthesia and respiratory devices, electrocardiographs, pulse oximeters and other in are not subject to trials in order to be approved as measuring tools for the purposes of their state registration, since these means are not included in the list of medical devices related to measuring tools in the area of state regulation of traceability approved by the Order of the Ministry of Healthcare of the Russian Federation, dated 15 August 2012, No. 89n.

It is also noted that the regional healthcare authorities and healthcare institutions are not authorized to take decisions on conducting trials of medical devices for the purpose of approval of measuring tools type, and to approve measuring tools type.

The Ministry of Healthcare of the Russian Federation in coordination with the Ministry of Industry defines the measurement related to the state regulation of traceability in the domain of healthcare and establishes obligatory metrological requirements thereto, including measurement accuracy factors.

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