The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

COURTESY TRANSLATION

GENERAL OVERVIEW QUESTIONNAIRE ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

Answers of the Russian Federation

As adopted by the Bureau of the MEDICRIME Committee on 7 July 2020

Replies should be addressed to the MEDICRIME Committee Secretariat by **23 September 2020** (**medicrime@coe.int**)

I. INTRODUCTION

II. PRELIMINARY REMARKS

Public authorities/institutions which responsible for collecting answers to the questions of this questionnaire:
Federal Service for Surveillance in Healthcare (Roszdravnadzor)

Public authorities/institutions which contribute to these answers:

- **The Ministry of Health of the Russian Federation (Minzdrav of Russia)**
- **Federal Service for Surveillance in Healthcare (Roszdravnadzor)**
- **The Prosecutor General's Office of the Russian Federation**
- **Federal Customs Service of Russia**
- **Ministry of Internal Affairs of the Russian Federation (MIA of Russia)**

III. GENERAL FRAMEWORK

Question 1: Definitions

a. Does the understanding of "medical product" under your internal law correspond to that set out in **Article 4, letter (a),** i.e. "medicinal products and medical devices"?

There is no definition of the term "medical product" in Russian legislation. All Russian legal acts contain the terms "medicinal product" and / or "medical device.

b. Does the understanding of “medicinal product” under your internal law correspond to that set out in **Article 4, letter (b)**, i.e. “medicines for human and veterinary use which may be:
   i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
   ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;
   iii. an investigational medicinal product”?

Corresponds.

Article 4 of the Federal Law of 12.04.2010 N 61-FZ "On the circulation of medicinal products": *"Medicinal products are substances or their combinations that come into contact with the human or animal body, penetrate*

the organs, tissues of the human or animal body, used for prophylaxis, diagnostics (with the exception of substances or their combinations that are not in contact with the human or animal body), treatment of diseases, rehabilitation, for the preservation, prevention or termination of pregnancy and obtained from blood, blood plasma, from organs, tissues of the human or animal body, plants, minerals by methods of synthesis or using biological technologies. Medicinal products include active substances and medicines"

c. Does the understanding of “active substance” under your internal law correspond to that set out in **Article 4, letter (c)**, i.e. “any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product”?

Corresponds.

Article 4 of the Federal Law of 12.04.2010 N 61-FZ "On the circulation of medicinal products": *"Active substance is a medicinal product in the form of one or more active ingredient with pharmacological activity, regardless of the nature of the origin, which is intended for the production, manufacture of medicines and determines their effectiveness"*

d. Does the understanding of “excipient” under your internal law correspond to that set out in **Article 4, letter (d)**, i.e. “any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product”?

Corresponds.

Article 4 of the Federal Law of 12.04.2010 N 61-FZ ""On the circulation of medicinal products": «*excipients are substances of inorganic or organic origin used in the production process, manufacturing of medicines to give them the necessary physical and chemical properties*»

e. Does the understanding of “medical devices” under your internal law correspond to that set out in **Article 4, letter (e)**, i.e. “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii. investigation, replacement or modification of the anatomy or of a physiological process;
iv. control of conception;
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"?

Corresponds.

Article 38, p. 1 of the Federal Law of 21.11.2011 N 323-FZ (as amended on 31.07.2020) "On the basics of health protection of citizens in the Russian Federation": *"Medical devices are any tools, apparatus, devices, equipment, materials and other products used for medical purposes separately or in combination with each other, as well as together with other accessories necessary for the use of these products for their intended purpose, including special software, and intended by the manufacturer for the prevention, diagnosis, treatment and medical rehabilitation of diseases, monitoring the state of the human body , carrying out medical research, restoration, replacement, changes in the anatomical structure or physiological functions of the body, prevention or termination of pregnancy, the functional purpose of which is not realized by pharmacological, immunological, genetic or metabolic effects on the human body"*

Currently, the harmonization of national legislation is being carried out with the legislation of the Eurasian Economic Union, which provides the following definition:

"Medical devices - any instruments, apparatus, devices, equipment, materials and other products that are used for medical purposes separately or in combination with each other, as well as with accessories necessary for the use of these products for their intended purpose (including special software), are intended by manufacturer for the prevention, diagnosis, treatment of diseases, medical rehabilitation and monitoring of the state of the human body, medical research, restoration, replacement, changes in the anatomical structure or physiological functions of the body, prevention or termination of pregnancy and the functional purpose of which is not realized by pharmacological, immunological, genetic or metabolic effects on the human body, however, it can be assisted by means of medicinal products" (Agreement on uniform principles and rules for the circulation of medical devices (medical devices and medical equipment) within the framework of Eurasian Economic Union (Ratified by Federal Law of 31.01.2016 N 4-FZ)

f. Does the understanding of "accessory" under your internal law correspond to that set out in **Article 4, letter (f)**, i.e. "an article which whilst not being a medical device is

designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device"?

Corresponds.

p. 3.2 GOST 31508-2012 "Medical devices. Classification according to the potential risk of use. General requirements": *"Accessories are items that are not independently medical devices and are used for their intended purpose in conjunction with a medical device or in their composition so that a medical device can be used in accordance with its intended purpose*".

g. Do the understanding of "parts" and "materials" under your internal law correspond to that set out in **Article 4, letter (g)**, i.e. "all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof"?

Corresponds.

Material is any synthetic or natural polymer, metal, alloy, ceramic or other non-viable material, including non-viable biological tissue, used as a medical device or part thereof. (p. 2.2 GOST ISO 10993-1-2011 Medical devices. Evaluation of the biological effect of medical devices. Part 1. Evaluation and researches").

A spare part is a component part of a product intended for replacing the same part that was in operation in order to maintain or restore the good condition or operability of the product (GOST 18322-78 "System of technical maintenance and repair of equipment. Terms and definitions").

A spare part is a separate unit, device or element designed to replace worn out, faulty or failed component parts of an object in order to maintain or restore its working condition (article 3.5.14 GOST 27.002-2015 "Reliability in technology (SSNT). Terms and definitions").

Spare parts, tools and accessories (SPTA) - a set of stocks of material resources, formed depending on the purpose and features of the use of the object and intended for its operation, maintenance and repair (article 3.5.15 GOST 27.002-2015 "Reliability in technology (SSNT). Terms and definitions").

Consumable materials are materials and products intended for periodic replacement, after the operating time or time intervals established in the operational documentation, as well as for servicing and maintaining the health of the medical devices (clause 3.4 GOST R 57501-2017 "Maintenance of medical devices. Requirements for public procurement ").

h. Does the understanding of “document” under your internal law correspond to that set out in **Article 4, letter (h)**, i.e. “any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof”?

Criminal liability for counterfeiting documents for medicinal products or medical devices or packaging of medicinal products or medical devices is established by Article 327.2 of the Criminal Code of the Russian Federation:
‘‘Article 327.2. Falsification of documents for medicinal products or medical devices or packaging of medicinal products or medical devices

1. Manufacturing for the purpose of using or selling, or using, of knowingly falsified documents for medicinal products or medical devices (registration certificate, certificate or declaration of conformity, instructions for the use of a medicinal product or regulatory, technical and operational documentation of the manufacturer (producer) of a medical device), -

shall be punishable by a fine in the amount of five hundred thousand to one million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to two years, or compulsory labor for a term of up to three years, or imprisonment for the same term.

2. Manufacturing for the purpose of using or selling, or using, of knowingly counterfeit primary packaging and (or) secondary (consumer) packaging of a medicine -

shall be punishable by a fine in the amount of five hundred thousand to one million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to two years, or compulsory labor for a term of up to three years, or imprisonment for the same term.

3. The commission of the acts provided for in the first or second parts of this Article by an organized group -

shall be punishable by imprisonment for a term of five to ten years with deprivation of the right to hold certain positions or engage in certain activities for a term of up to three years. "

From our point of view, the term “document” in this article of the Criminal Code of the Russian Federation generally corresponds to that in p. “h” of Article 4 of the Convention. The disposition itself reveals the manufacture, sale, the use of which counterfeit documents presents a crime - these are a registration certificate, a certificate or declaration of conformity, instructions for the use of a medicinal product or regulatory, technical and operational documentation of the manufacturer (producer) of a medical device, as well as primary and secondary packaging medicinal product.

i. Does the understanding of “manufacturing” under your internal law correspond to that set out in **Article 4, letter (i)**, i.e.
    i. “as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;
    ii. as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;
    iii. as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state”?

Corresponds.

i. Article 4 of the Federal Law of 12.04.2010 N 61-FZ ""On the circulation of medicinal products": *“manufacturing of medicinal products - activities for the manufacture of medicinal products by organizations - manufacturers of medicinal products at one stage, several or all stages of the technological process, as well as storage and sale of manufactured medicinal products”*. Medicinal products include active substances and medicines (see question 1.b).

ii. According to Article 38 of the Federal Law of 21.11.2011 N 323-FZ «On the basics of health protection of citizens in the Russian Federation» the manufacturing of medical devices is part of the circulation of medical devices. This act provides for the obligation of manufacturers of a medical device to develop technical and (or) operational documentation, in accordance with which the manufacturing, production, storage, transportation, installation, adjustment, use, operation, including maintenance, as well as repair, disposal or destruction of a medical device.

The legislation of the Eurasian Economic Union provides the following definition *"A manufacturer of a medical device is a legal person or an individual registered as an individual entrepreneur responsible for the development and manufacture of a medical device, making it available for use on its own behalf, regardless of whether a medical device is developed and (or) manufactured by this person or on his behalf by another person (persons), and who are responsible for the safety, quality and effectiveness of a medical device*"(p. 3 of the Rules for registration and examination of safety, quality and effectiveness of medical devices, approved by the Decision of the Council of the Eurasian Economic Commission of 12.02.2016 N 46).

iii. in relation to the accessory

"Stage of production (manufacturing) is works aimed at ensuring the release of new (modernized, modified) products that meet the requirements of the technical specifications, design and technological documentation" (p. 4.5 GOST R 15.000-2016 "System for the development and launch of products (SRPP). The framework"). The definition covers the process of manufacturing accessories.

j. Does the understanding of “counterfeit” under your internal law correspond to that set out in **Article 4, letter (j)**, i.e. “a false representation as regards identity and/or source”?

Article 4 of the Federal Law of 12.04.2010 N 61-FZ ««On the circulation of medicinal products»: "*falsified medicinal product is a medicinal product accompanied by false information about its composition and (or) manufacturer"*

Article 38, p. 1 of the Federal Law of 21.11.2011 N 323-FZ «On the basics of health protection of citizens in the Russian Federation»: *"A falsified medical device is a medical device accompanied by false information about its characteristics and (or) the manufacturer (producer)"*

k. Does the understanding of “victim” under your internal law correspond to that set out in **Article 4, letter (k)**, i.e. “any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8”?

Corresponds (and is broader).

In accordance with Article 42, p. 1 of the Criminal Procedure Code of the Russian Federation, “*victim is a natural person, to whom a physical, property or moral harm was caused by the crime, as well as a legal person, whose property and business reputation were damaged by the crime. The decision on recognizing a person as a victim shall be made right after initiating a criminal matter and shall be documented by a resolution of the inquirer, investigator and judge or by the court ruling. If at the moment of initiation of a criminal case no information is available about the person who was harmed by the crime, the decision on recognition as a victim shall be made immediately after the information about this person becomes known”.*

Also, article 25.2 of the Code of Administrative Offenses of the Russian Federation establishes that the victim is a natural or a legal person who was harmed physically, property or morally by an administrative offense.

Question 2: Non-discrimination

Is discrimination, on grounds such as the ones mentioned in the indicative list in **Article 2**, prohibited in the implementation of the Convention, in particular in the enjoyment of the rights guaranteed by it? If so, please specify. If not, please justify.

In the Russian Federation, according to Article 19 of the Constitution, everyone is equal before the law and the court; the state guarantees the equality of human and civil rights and freedoms regardless of gender, race, nationality, language, origin, property and official status, place of residence, attitude to religion, beliefs, membership of public associations, and other circumstances. Any form of restriction of the rights of citizens on the basis of social, racial, national, linguistic or religious affiliation is prohibited.

Thus, the provisions on equal rights and freedoms of citizens and on equal opportunities for their implementation are enshrined at the constitutional level.

Discrimination (in its general form) is a criminal offense that carries penalties up to and including imprisonment. Article 136 "Violation of the equality of human and civil rights and freedoms" of the Criminal Code of the Russian Federation states:

"Discrimination, that is, violation of the rights, freedoms and legal interests of person and citizen based on sex, race, nationality, language, origin, property or official status, place or residence, attitude to religion, convictions, or affiliation with public associations or any social groups, -

shall be punishable with a fine in the amount of 100 thousand to 300 thousand rubles, or in the amount of a wage or salary, or any other income of the convicted person for a period of one year to two years, or by deprivation of the right to hold specified offices or engage in specified activities for a term of up to five years, or by obligatory labor for a term of up to four hundred and eighty hours, or by corrective labor for a term of up to two years, or by imprisonment for the same term".

Question 3: Overview of the implementation

Please indicate (without entering into details):

a. the main legislative or other measures to combat counterfeiting of medical products and similar crimes involving threats to public health in accordance with the Convention;

The legislation of the Russian Federation prohibits:

- manufacturing of counterfeit medicinal products (Article 45, p.5 of Law N 61-FZ);
- import of falsified medicinal products, substandard medicinal products, and counterfeit medicinal products into the Russian Federation (Article 47, p.5 of Law N 61-FZ);
- sale of falsified medicinal products, substandard medicinal products, and counterfeit medicinal products into the Russian Federation (Article 57 of Law N 61-FZ);
- manufacturing of falsified medical devices (Article 38, p. 15 of Law N 323-FZ),
- import to the territory of the Russian Federation of falsified medical devices, substandard medical devices and counterfeit medical devices (Article 38, p. 15 of Law N 323-FZ),
- sale of falsified medical devices, substandard medical devices and counterfeit medical devices (part 17 of article 38 of Law N 323-FZ).

Federal Law of 22.12 2014 N 429-FZ "On amending the Federal Law on the circulation of medicinal products" revised the rules on the organization of state control and supervision of the quality of medicinal products, significantly expanded the powers of the responsible Federal Executive authorities in terms of state control and supervision over the circulation of medicinal products, introduced the mechanisms for selective quality control of medicinal products and established centralized collection of data on all batches of medicinal products introduced into civil circulation on the territory of the Russian Federation. The current system of state quality control allows identifying and prompt blocking the turnover of medicinal products that do not meet the established requirements, thereby preventing the safety of patients.

In order to counteract the circulation of falsified, counterfeit and substandard medicinal products, the Russian Federation has created the appropriate infrastructure of the state control system.

In preparation for the ratification by the Russian Federation of the MEDICRIME Convention by the Federal Law of 31.12.2014 N 532-FZ "On amendments to certain legislative acts of the Russian Federation with regard to combating the circulation of falsified, counterfeit, substandard and unauthorized these are, medical devices and counterfeit dietary supplements" amendments have been made to the Criminal Code of the Russian Federation and the Code of Administrative Offences of the Russian Federation, measures of responsibility for offenses and crimes related to illegal circulation of substandard, falsified and unauthorized pharmaceutical and medical products were established.

Federal Laws of 01.04.2020 N 89-FZ "On amendments to the Code of Administrative Offenses of the Russian Federation" and N 95-FZ "On amendments to Article 238.1 of the Criminal Code of the Russian Federation" increased liability for the circulation of falsified, counterfeit, substandard and unauthorized medicinal products using the mass media or electronic or information - telecommunication networks, including the Internet.

Federal Law N 511-FZ of 27.12.2018 "On amendments to certain legislative acts of the Russian Federation" amended Article 9 of Law N 61-FZ, according to which federal state supervision in the field of medicinal products circulation includes conducting test purchases for the purpose of verification of compliance by the subjects of medicinal products circulation, engaged in retail trade of medicinal products for human use, with the rules for dispensing medicinal products for human use and (or) the prohibition of the sale of falsified medicinal products, substandard medicinal products and counterfeit medicinal products.

In pursuance of the Instruction of the President of the Russian Federation V.V. Putin of 04.02.2015 on the development and phased implementation of an automated system for monitoring the movement of medicinal products from the manufacturer to the end consumer using labeling and identification of packages of medicinal products, in order to ensure effective quality control of medicinal products in circulation and to combat counterfeiting (Track & Trace system), Federal Law N 425-FZ of 28.12.2017 "On amendments to the Federal Law "On the circulation of medicinal products" was adopted.

Federal Law N 425-FZ of 28.12.2017 "On amendments to the Federal Law "On the circulation of medicinal products" established the deadline for the introduction of mandatory labeling of medicinal products for the Track & Trace system – July 1, 2020.

According to Article 67, p. 7 of Law N 61-FZ, legal persons and individual entrepreneurs engaged in the manufacturing, storage, import into the Russian Federation, dispensing, sale, transfer, use and destruction of medicines for human use ensure the entry of information on medicinal products for human use to the system for monitoring the movement of medicinal products for human use (Track & Trace system).

Article 6.34 of the Code of Administrative Offenses of the Russian Federation establishes the liability for late entry of data into the system for monitoring the movement of medicinal products for human use or entering inaccurate data into it -

«entails the imposition of an administrative fine on officials in the amount of five thousand to ten thousand rubles; on legal persons - from fifty thousand to one hundred thousand rubles».

In pursuance of the Instruction of the President of the Russian Federation, Federal Law N 449-FZ of 28.11.2018 "On amendments to certain legislative acts of the Russian Federation on the issue of introduction of medicines for human use into civil circulation" aimed at improving legal regulation in the field of circulation medicines for human use, was developed.

Manufacturers or importers of medicinal products, prior to the introduction into civil circulation of each batch or each lot of a medicinal product, must submit to Roszdravnadzor documents confirming the quality of the medicinal product, or documents certifying the compliance of the medicinal product with the requirements established during its state registration.

For the first three batches or lots of a medicinal product first produced in the Russian Federation (imported to the Russian Federation for the first time), an additional protocol of analysis issued by federal laboratories, confirming the compliance of the batch or lot of a medicine with quality indicators must be submitted.

In accordance with Article 351 of the Customs Code of the Eurasian Economic Union, the customs authorities, within their competence, ensure compliance with prohibitions and restrictions on goods moved across the customs border of the Eurasian Economic Union (EAEU).

Medicinal products are included in section 2.14 of the unified list of goods subject to non-tariff regulation in trade with third countries, and their import is carried out in accordance with the Regulations on the import of medicinal products to the customs territory of the EAEU (hereinafter referred to as the Regulations to section 2.14).

According to p. 5 of the Regulations to section 2.14, authorized medicinal products are placed under the customs procedure for release for domestic consumption when the customs authority of the EAEU member state is provided with information on the inclusion of medicinal products in the unified register of authorized medicinal products of the EAEU, provided by article 14 of the Agreement on common principles and rules for the circulation of medicinal products within the framework of the Eurasian Economic Union or in the corresponding state register of medicinal products (GRLS) of the EAEU member state. State register of authorized medicinal products (GRLS) of the Russian Federation is managed by the Ministry of Health of the Russian Federation.

b. Whether your country has adopted a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health. If so, please specify the main fields of action and the body/bodies responsible for its/their implementation;

Yes.

In pursuance of the Decree of the President of the Russian Federation N 598 of 07.05.2012 "On improving state health policy", Order N 66 of the Ministry of Health of the Russian Federation of 13.02.2013 approved the Strategy for Providing Medicinal Products to the Population of the Russian Federation for the period up to 2025 and its implementation plan. As part of the implementation of this policy, consistent work is being carried out to improve the state control and licensing system in the field of ensuring and monitoring the quality, effectiveness and safety of medicinal products for human use at all stages of their circulation, as well as combating the circulation of counterfeit and substandard medicinal products for human use.

The draft decree of the Government of the Russian Federation on approval of the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030 sets a priority for the manufacturing of high-quality, effective and safe pharmaceutical products, and preventing the turnover of falsified, counterfeit and sub-standard products.

The Strategy for the Development of the Medical Industry of the Russian Federation for the period up to 2020 outlines the priority of ensuring the quality and safety of manufactured medical devices and the development of quality control mechanisms.

c. If there has not been any adoption of a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to

public health, whether there is a strategy and /or Action Plan by a particular Ministry or State Agency that leads on this nationally.

Question 4: National co-operation and information exchange

a. Please describe how co-operation and exchange of information is ensured between representatives of health authorities, law-enforcement (e.g. police and customs authorities) and other competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health (**Article 17, para. 1**).

As part of the Agreement on Interaction between the Federal Service for Surveillance in Healthcare and the Federal Customs Service of 10.09.2013, when providing and receiving information, the Federal Customs Service of Russia sends to Roszdravnadzor, at its request, data on cases of administrative offenses (hereinafter referred to as AO) concerning the movement of goods, whose supervision belongs to the established sphere of activity of Roszdravnadzor.

Roszdravnadzor within the framework of this Agreement sends to the Federal customs service of Russia:

quarterly – information about active substances with manufacturer's certificates that do not meet the requirements, or about recipients of active substances;

monthly - information about detected substandard medicinal products.

Based on the data obtained, the Federal Customs Service of Russia forms risk profiles, according to which Roszdravnadzor conducts control and supervisory measures.

The Federal Customs Service of Russia and the Ministry of Health of the Russian Federation organized interdepartmental electronic interaction, within the framework of which the customs authorities, when performing customs operations related to the declaration of medicinal products, receive information about the permits contained in the information resources of the Ministry of Health of the Russian Federation in an automatic mode close to real time.

An agreement was signed on the procedure for interaction between Roszdravnadzor and the Ministry of Internal Affairs of Russia in terms of countering the circulation of falsified, counterfeit, substandard and unauthorized medicinal products and medical devices, within the framework of which Roszdravnadzor sends information to the Ministry of Internal Affairs of Russia that indicates violations related to the circulation of falsified, counterfeit,

substandard and unauthorized medicinal products and medical devices and containing signs of crimes attributed to the competence of the internal affairs bodies of the Russian Federation.

The Ministry of Internal Affairs of Russia, upon revealing the facts of circulation of possibly falsified, counterfeit, substandard and unauthorized medicinal products and medical devices, send samples of these medicinal products and medical devices to Roszdravnadzor.

The Ministry of Internal Affairs of Russia, if it is necessary to draw up an expert opinion on the presence in the product of a certain name of signs of an unauthorized medicine or medical device, sends a request to Roszdravnadzor about the possibility of conducting an examination in laboratories subordinate to Roszdravnadzor. Expert opinions are sent by Roszdravnadzor to the Ministry of Internal Affairs of Russia within 5 working days after receiving the research results.

b. Is any form of cooperation between the competent authorities and the commercial and industrial sectors promoted as regards risk management of counterfeit medical products and similar crimes involving threats to public health? (**Article 17, para. 2**)?

By decree of the President of the Russian Federation N 31 of 23.01.2015 "On additional measures to counteract the illegal turnover of industrial products", the State Commission for Combating the Illegal Turnover of Industrial Products was established to coordinate the activities of Federal executive authorities, executive authorities of the territory subjects of the Russian Federation and local self-government bodies to combat illegal import, manufacturing and circulation of industrial products, including counterfeit ones, as well as to monitor and assess the situation in this area on the territory of the Russian Federation. The Chairman of the Commission is the Minister of industry and trade of the Russian Federation.

Under the chairmanship of the First Deputy Minister of industry and trade of the Russian Federation, meetings of the Interdepartmental Sectoral Working Group on Combating Illegal Circulation of Pharmaceutical and Medical Products which includes representatives of federal executive authorities and industry, are regularly held.

c. Which legislative or other structured measures have been taken to set up or strengthen mechanisms for:
    - receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the

counterfeiting of medical products and similar crimes involving threats to public health? (**Article 17, para. 3, letter (a)**)?

Article 9 of the Federal Law of 12.04.2010 N 61-FZ "On the circulation of medicinal products" provides selective control of the quality of medicinal products by processing information that is mandatory submited by the subjects of medicinal products circulation, about series, batches of medicinal products entering civil circulation in the Russian Federation, and selection of samples of medicinal products from subjects of circulation of medicinal products for the purpose of conducting tests for their compliance with the requirements of normative documentation or regulatory documents.

In accordance with the Order of the Ministry of industry and trade of Russia of 14.06.2013 N 916 "On approval of the rules of Good Manufacturing Practice", the manufacturer must organize a system for recalling any batch of medicinal product from circulation (p. 14.k), The manufacturer should regularly review the quality of all products manufactured, and the review should include an overview of all product-related returns, claims and reviews, as well as investigations conducted at that time (p.17.s).

When considering claims and information related to potentially substandard medicinal products, the manufacturer should pay special attention to assessing whether the cause of the claim is falsification of products (p. 263 of the Order of 14.06.2013 N 916).

If the manufacturer takes actions that are the result of possible errors in production, decline of product quality, identification of counterfeit products or other serious problems related to product quality, the relevant authorized Federal Executive authority must be informed (item 264 of the Order of 14.06.2013 N 916).

Information about counterfeit and substandard medicinal products and medical devices detected and withdrawn from circulation is publicly available on the Roszdravnadzor website: https://roszdravnadzor.gov.ru/services/lssearch.

P. 45 of the Rules of Good Practice for the Storage and Transportation of Medicinal products for Human Use, approved by Order of the Ministry of Health of Russia N 646n of 31.09.2016, stipulates that the subject of medicinal products circulation is taking measures to minimize the risk of falsified, counterfeit, substandard medicinal products entering circulation.

In order to comply with these requirements, the subjects of medicinal products circulation (pharmacies, organizations engaged in wholesale trade in medicinal products, medical organizations) may use the information posted on the official website of Roszdravnadzor.

- making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them? (**Article 17, para. 3, letter (b)**)?

Agreements and Algorithms for cooperation and information exchange in the field of prevention of circulation of counterfeit medicines and medical devices are signed between Roszdravnadzor, the Ministry of Internal Affairs of the Russian Federation and Federal Customs Service of Russia. (see question 4a).

d. Please indicate the persons, units or services in charge of this co-operation and information exchange in the field of the MEDICRIME Convention. Please indicate how they are trained for this purpose and how resources are secured for it/them (**Article 17, para. 4)**.

According to the above mentioned agreements information exchange is performed between:

- Federal Service for Surveillance in Healthcare (Roszdravnadzor): Department for Organization of State Quality Control of Medical Products, Department for Organization of State Control and Registration of Medical Devices.
- Ministry of Internal Affairs of the Russian Federation: Main Directorate of Economic Security and Anti-Corruption.
- Federal Customs Service.
- Ministry of Healthcare of the Russian Federation

Information on trainings will be provided in the answer to question 13c.

Sources of obtaining the necessary information:

– selection of samples of medical products as part of verification activities, test purchases, sampling;
– test results of selected samples in state laboratories;
– information received from subjects of circulation of medicinal products and medical devices;
– information received from citizens;
– information obtained in the course of information exchange between Roszdravnadzor, the Ministry of Internal Affairs of Russia and the Federal Customs Service of Russia (see question 4a).

Question 5: International cooperation

a. Please indicate the national contact point responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health (**Article 22, para. 2**).

In accordance with Federal law N 439-FZ of 29.12.2018 "On ratification of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health", the Federal Service for Surveillance in Healthcare (Roszdravnadzor) is the national contact point, responsible for transmitting and receiving requests for information and (or) cooperation in the fight against falsification of medical products and similar crimes involving threats to public health, with the exception of requests for extradition and legal assistance in criminal cases.

b. Has your country integrated prevention and the fight against counterfeiting of medical products and similar crimes involving threats to public health in assistance programmes for development provided for the benefit of third states (**Article 22, para. 3**)? Please give examples.

By the decision of the Council of the Eurasian Economic Commission of 03.11.2016 N 86, the Procedure for interaction of the member states of the Eurasian Economic Union to identify falsified, counterfeit and (or) substandard medicinal products was adopted. Information interaction is carried out in the mode of prompt notification of the Eurasian Economic Commission (within 72 hours from the moment of establishing the fact that the medicinal product is classified as falsified or counterfeit) or upon request for information.

In order to combat smuggling, including in the field of illegal movement of counterfeit medical products across the EAEU customs border, on the basis of the Federal Customs Service of Russia in accordance with the decision of the Council of Heads of Customs Services of the Member States of the Commonwealth of Independent States N 7/64 of 15.09.2016 the regional communication center for law enforcement work of the World Customs Organization for the CIS countries operates a 24/7 contact point based on the international law enforcement communication platform of the World Customs Organization CENcomm.

Within the framework of international special customs operations, closed user groups are created on the CENcomm platform to exchange proactive and other law enforcement information about possible upcoming, committed and detected offenses in relation to the objects of operations.

In 2008, the governments of the member states of the Commonwealth of Independent States signed an Agreement on cooperation in combating the circulation of counterfeit medicinal products. According to Article 3 of the

Agreement, the parties commit to inform each other about the facts of detection and distribution of counterfeit medicinal products, methods of protecting medicinal products and methods of confirming the authenticity of medicinal products.

The issue of counteracting the circulation of counterfeit products is included in the agendas of meetings of intergovernmental commissions on trade, economic and scientific and technical cooperation between the Russian Federation and foreign countries.

The Ministry of Internal Affairs of Russia, Federal Security Bureau of Russia, Federal Customs Service of Russia, Roszdravnadzor annually take part in the Pangea international police operation aimed at combating crimes in the field of illegal circulation of medical products. The coordinator of the operation on the territory of the Russian Federation is the National Central Bureau of Interpol of the Ministry of Internal Affairs of Russia. Representatives of Roszdravnadzor, Ministry of Health of Russia, Ministry of Internal Affairs of Russia, Federal Security Bureau of Russia take part in the work of international initiatives to identify and prevent the spread of counterfeit medical products, such as, CMED, WGEO, APEC, WHO Member State Mechanism to address the issue of SF medical products.

IV. PROSECUTION OF CULPRITS OF COUNTERFEIT OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 6: Criminal Law offences

a. Please indicate whether the intentional conducts in the box below are considered criminal offences in internal law.

Article 5 of the Convention. Manufacturing of counterfeits.

Article 238.1 of the Criminal Code of the Russian Federation (*implementation of Article 5, p.1 of the Convention*) establishes the criminal liability for the manufacturing of counterfeit medicinal products or medical devices, illegal manufacturing of unauthorized medicinal products or medical devices, and manufacturing of counterfeit dietary supplements containing active substances not declared during state registration. The manufacturing of medicinal products or medical devices without a special permit (license), if such permission (such license) is mandatory, is punishable under article 235.1 of the Criminal Code of the Russian Federation *("adulteration", Article 5, p.2 of the Convention).*

"Article 235.1 Illegal manufacturing of medicinal products and medical devices

1. Manufacturing of medicinal products or medical devices without a special permit (license), if such a permit (such license) is mandatory, -

shall be punishable by imprisonment for a term of three to five years, with or without a fine in the amount of five hundred thousand to two million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of six months to two years.

2. The same acts committed:

a) by an organized group;

b) on a large scale, -

shall be punishable by imprisonment for a term of five to eight years, with or without a fine in the amount of one million to three million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to three years.

Note. A large scale in this article is the cost of medicinal products or medical devices in excess of one hundred thousand rubles".

"Article 238.1 Circulation of counterfeit, substandard and unauthorized medicinal products, medical devices and circulation of counterfeit dietary supplements

1. Manufacturing, sale or import into the territory of the Russian Federation of counterfeit medicinal products or medical devices, or sale or import into the territory of the Russian Federation of substandard medicinal products or medical devices, or illegal manufacturing, sale or import into the territory of the Russian Federation of unauthorized medicinal products or medical devices for the purpose of sale, or the manufacturing, sale or import into the territory of the Russian Federation of counterfeit dietary supplements containing active substances not declared during state registration, committed on a large scale -

shall be punishable by obligatory labor for a term of three to five years with or without deprivation of the right to hold certain positions or engage in certain activities for a term of up to three years, or by imprisonment for a term of three to five years, with a fine in the amount of five hundred thousand to two million rubles, or in the amount of the wage or salary or other income of the convicted person for a period from six months to two years or without it and with the deprivation of the right to hold certain positions or engage in certain activities for a period of up to three years or without it.

1.1. The acts provided for in the first part of this Article, committed with the use of mass media or information and telecommunication networks, including the Internet, -

shall be punishable with obligatory labor for a term of four to five years with or without deprivation of the right to hold certain positions or engage in certain activities for a term of two to three years, or imprisonment for a term of four to six years with a fine in the amount of seven hundred fifty thousand to two million five hundred thousand rubles or in the amount of the wage or salary or other income of the convicted person for a period of one to two years or without it and with the deprivation of the right to hold certain positions or engage in certain activities for a period of up to four years or without it.

2. The acts provided for in parts one or one.1 of this article, if they:

a) are committed by a group of persons in a preliminary agreement or by an organized group;

b) entailed, through negligence, the infliction of grievous bodily harm or the death of a person, -

shall be punishable by imprisonment for a term of five to eight years, with a fine in the amount of one million to three million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to three years, or without such, and with deprivation of the right to hold certain positions or practice certain activities for up to five years or without.

3. The acts provided for in first, first.1 or second parts of this Article, and entailed the death of two or more persons by negligence, -

shall be punishable by imprisonment for a term of eight to twelve years, with a fine in the amount of two million to five million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of two to five years, or without such, and with the deprivation of the right to hold certain positions or practice certain activities for up to ten years or without.

Notes.

1. This article does not apply to cases of illegal sale and import into the territory of the Russian Federation of narcotics, psychotropic substances, their precursors, highly potent or poisonous substances, as well as illegal manufacturing of narcotics, psychotropic substances or their precursors.

2. A large scale in this article is the cost of medicinal products, medical devices or dietary supplements in excess of one hundred thousand rubles.

3. This article does not apply to cases of sale and (or) import into the territory of the Russian Federation medicinal products or medical devices unauthorized in the Russian Federation for the purpose of selling, if the said

medicinal products or medical devices are not produced in the Russian Federation, and (or) if the sale and (or) import of such medicinal products or medical devices is allowed in accordance with the legislation on the circulation of medicinal products and legislation in the field of health protection respectively, and (or) if these medicinal products or medical devices are recommended for use by the World Health Organization. "

In addition, if a certain item does not fall under the signs of a medical device (as defined by Federal Law N 323-FZ of 21.11.2011), but is used as an accessory, the manufacturing of such a substandard product, if there are grounds for that, may entail bringing the culprits to criminal liability under Article 238 of the Criminal Code of the Russian Federation:

«Article 238. Manufacturing, storage, carriage or sale of goods and products, fulfillment of works or rendering of services that do not meet safety standards

1. Manufacturing, storage or carriage for the purpose of sale or sale of goods and products, performance of work or provision of services that do not meet the standards of safety of life or health of consumers, as well as the illegal issuance or use of an official document certifying the compliance of these goods, works or services with safety standards, -

shall be punishable by a fine in an amount of up to three hundred thousand rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of up to two years, or by obligatory labor for a term of up to three hundred and sixty hours, or imprisonment for a term of up to two years, or compulsory works for a term of up to two years, or imprisonment for the same period.

2. The same acts if they:

a) are committed by a group of persons in a preliminary conspiracy or by an organized group;

b) are committed in relation to goods, works or services intended for children under the age of six;

c) entailed, through negligence, the infliction of grievous bodily harm or the death of a person, -

shall be punishable by a fine in the amount of one hundred thousand to five hundred thousand rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to three years, or obligatory labor for a term of up to five years, or imprisonment for a term of up to six years, with a fine in the amount of up to five hundred thousand rubles or in the amount of the wage or salary, or other income of the convicted person for a period of up to three years or without it.

3. The acts provided for in the first or second part of this Article, which, through negligence, entailed the death of two or more persons, -

shall be punishable by compulsory works for a term of up to five years, or imprisonment for a term of up to ten years."

Article 6 of Convention. Supplying, offering to supply, and trafficking in counterfeits.

Criminal liability for the sale or import into the territory of the Russian Federation of counterfeit or substandard medical products is provided for by the previously mentioned article 238.1 of the Criminal Code of the Russian Federation.

As for the storage and export of such products, such actions, depending on the actual circumstances, may be covered by the intention of the culprit to manufacture, sell, import falsified products, or, if there are grounds for obtaining a criminal-legal assessment under other articles of the Special Part of the Criminal Code of the Russian Federation.

With regard to "intermediary operations", the information is indicated in the reply to article 9 of the Convention.

Article 7 of Convention. Falsification of documents.

The criminal legislation of the Russian Federation recognizes falsification of documents for medicinal products or medical devices, or packaging of medicinal products or medical devices, and provides for a punishment of up to 10 years in prison.

"Article 327.2. Falsification of documents for medicinal products or medical devices or packaging of medicinal products or medical devices

1. Manufacturing for the purpose of using or selling, or using, of knowingly falsified documents for medicinal products or medical devices (registration certificate, certificate or declaration of conformity, instructions for the use of a medicinal product or regulatory, technical and operational documentation of the manufacturer (producer) of a medical device), -

shall be punishable by a fine in the amount of five hundred thousand to one million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to two years, or compulsory labor for a term of up to three years, or imprisonment for the same term.

2. Manufacturing for the purpose of using or selling, or using, of knowingly counterfeit primary packaging and (or) secondary (consumer) packaging of a medicine -

shall be punishable by a fine in the amount of five hundred thousand to one million rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of one to two years, or compulsory labor for a term of up to three years, or imprisonment for the same term.

3. The commission of the acts provided for in the first or second parts of this Article by an organized group -

shall be punishable by imprisonment for a term of five to ten years with deprivation of the right to hold certain positions or engage in certain activities for a term of up to three years."

Article 8 of Convention. Similar crimes involving threats to public health

From our point of view, the fairly universal norms of the Special Part of the Criminal Code of the Russian Federation allow, based on the results of the preliminary investigation, to give a legal assessment of any socially dangerous acts.

Article 9 of Convention. Aiding or abetting and attempt.

To the Article 9, p.1.

The institution of complicity in a crime is enshrined in Chapter 7 of the Criminal Code of the Russian Federation. The complicity in a crime is the intentional joint participation of two or more persons in the commission of an intentional crime. Organizer, abettor and aider are recognized as accomplices in the crime along with the culprit.

An abettor is a person who persuaded another person to commit a crime by persuasion, bribery, threat or in another way (part 4 of article 33 of the Criminal Code of the Russian Federation).

An aider is a person who assisted in the commission of a crime with advice, instructions, provision of information, means or instruments for committing a crime, or removing obstacles, as well as a person who promised in advance to hide the offender, means or instruments of committing a crime, traces of a crime or objects obtained by criminal means, as well as a person , who promised in advance to purchase or sell such items (part 5 of article 33 of the Criminal Code of the Russian Federation).

The responsibility of accomplices in a crime is determined by the nature and degree of the actual participation of each of them in the commission of the crime.

To the Article 9, p.2.

In accordance with Article 29 of the Criminal Code of the Russian Federation, preparation for a crime and attempted crime are recognized as an

unfinished crime. Criminal liability for an unfinished crime occurs under the article of the Criminal Code of the Russian Federation, which provides for liability for a completed crime, with reference to Article 30 of the Criminal Code of the Russian Federation.

Preparation for a crime is the search for, manufacture or adaptation by a person of means or instruments of committing a crime, seeking accomplices in a crime, conspiracy to commit a crime or other deliberate creation of conditions for committing a crime, if the crime has not been completed due to circumstances beyond the control of this person (Article 30, p.1 of the Criminal Code of the Russian Federation).

Criminal liability comes for preparation only for grave and especially grave crimes (Article 30, p.2 of the Criminal Code of the Russian Federation). This is a feature of Russian criminal law.

An attempted crime is the deliberate actions (inaction) of a person directly aimed at committing a crime, if the crime was not completed due to circumstances beyond the control of this person (Article 30, p.3 of the Criminal Code of the Russian Federation).

It should be noted that, according to Article 66 of the Criminal Code of the Russian Federation, the term or amount of punishment for preparation for a crime cannot exceed half of the maximum term or amount of the most severe type of punishment provided for by the corresponding article of the Special Part of the Criminal Code of the Russian Federation for a completed crime. For attempted crime, the upper limit is three quarters of the maximum term or the most severe type of punishment.

b. Do the offences in your internal laws require intentional conduct? If no, please provide information.

The subjective side of the above crimes (Articles 235.1, 238.1, 327.2 of the Criminal Code of the Russian Federation) is characterized by a deliberate form of guilt.

c. Please highlight whether there are any other offences not included in the box below that involves counterfeit of medical products and similar crimes involving threats to public health in your country? Please provide their definitions and specify in which act these are included.

Russian criminal law also establishes responsibility for crimes other than those listed above that threaten public health (Chapter 25 of the Criminal Code of the Russian Federation). Among them are such as:

Article 235. Unlawful practice of medical or pharmaceutical activities

Article 236. Violation of sanitary and epidemiological rules

Article 238. Manufacturing, storage, carriage or sale of goods and products, performance of work or provision of services that do not meet safety requirements.

The basis for criminal liability is the commission of an act containing all the elements of a crime provided for by the Criminal Code of the Russian Federation.

Question 7: Jurisdiction

With regard to the offences referred to in question 6, please indicate which jurisdiction rules apply. Please specify under which conditions, if required (**Article 10, Explanatory Report, paras. 69-78**).

The operation of the criminal law of the Russian Federation is regulated by Articles 11 and 12 of the Criminal Code of the Russian Federation:

«Article 11. The operation of the criminal law in respect to persons who have committed a crime on the territory of the Russian Federation

1. *Any person who has committed a crime on the territory of the Russian Federation shall be brought to criminal liability under this Code.*
2. *Crimes committed within the limits of the territorial sea or the airspace of the Russian Federation shall be deemed to have been performed on the territory of the Russian Federation. The validity of this Code shall also be extended to offences committed on the continental shelf and in the exclusive economic zone of the Russian Federation.*
3. *A person who has committed a crime on a craft registered in a port of the Russian Federation and situated on the open sea or in the airspace outside the confines of the Russian Federation shall be brought to criminal liability under this Code, unless otherwise is stipulated by an international agreement of the Russian Federation. Under this Code, criminal liability shall also be borne by a person who has committed an offence on board of a warship or a military aircraft of the Russian Federation, regardless of the place of their location.*
4. *The question of the criminal liability of diplomatic representatives of foreign States and other individuals who have immunity shall be settled in conformity with the norms of international law, if these persons have committed crimes on the territory of the Russian Federation.*

Article 12. The operation of the criminal law in respect to persons who have committed a crime outside the territory of the Russian Federation

1. Citizens of the Russian Federation and stateless persons permanently residing in the Russian Federation who have committed outside the Russian Federation a crime against the interests guarded by the present Code shall be subject to criminal liability in accordance with the present Code, unless a decision of a foreign state's court exists concerning this crime in respect of these persons.

2. Servicemen of military units of the Russian Federation located beyond the confines of the Russian Federation shall bear criminal liability for their crimes committed on the territories of foreign states under this Code, unless otherwise stipulated by international agreements of the Russian Federation.

3. Foreign nationals and stateless persons who do not reside permanently in the Russian Federation and who have committed crimes outside the boundaries of the Russian Federation shall be brought to criminal liability under this Code in cases where the crimes run against the interests of the Russian Federation or a citizen of the Russian Federation or a stateless person permanently residing in the Russian Federation, and also in the cases provided for by international agreements of the Russian Federation, and unless the foreign citizens and stateless persons not residing permanently in the Russian Federation have been convicted in a foreign state and are brought to criminal liability on the territory of the Russian Federation.

When ratifying the MEDICRIME Convention, the Russian Federation declared that, in accordance with Article 10, p.1, lett."d" of the Convention, it would prosecute foreign citizens and stateless persons permanently residing in its territory only in cases provided for by the Criminal Code of the Russian Federation (p. 1 of the Federal Law of 29.12.2017 N 439-FZ "On the ratification of the Council of Europe Convention on the fight against counterfeiting of medical products and similar crimes threatening public health").

Question 8: Corporate liability

Does your system provide that a legal person may be held liable for an offence established in accordance with **Article 11**? Please specify under which conditions.

The subject of any crime under Russian law is a natural person. There are no mechanisms for bringing legal persons to criminal responsibility. At the same time, there is a possibility of bringing legal persons to administrative responsibility.

For the manufacturing, sale or import into the territory of the Russian Federation of counterfeit medicinal products or medical devices, as well as counterfeit dietary supplements containing active substances not declared during state registration, legal persons are subject to administrative liability (Article 6.33 of the Code of Administrative Offenses of the Russian Federation):

« 1. Manufacturing, sale or import into the territory of the Russian Federation of counterfeit medicinal products, or manufacturing, sale or import into the territory of the Russian Federation of counterfeit medical devices, or sale or import into the territory of the Russian Federation of counterfeit medicinal products, or sale or import into the territory of the Russian Federation of counterfeit medical devices, or the circulation of counterfeit dietary supplements, with the exception of cases provided for by part 3 of this article, if these actions do not contain a criminal offense, -

shall incur an administrative fine on citizens in the amount of seventy thousand to one hundred thousand rubles; for officials - from one hundred thousand to six hundred thousand rubles; for individual entrepreneurs - from one hundred thousand to six hundred thousand rubles or administrative suspension of activities for up to ninety days; for legal persons - from one million to five million rubles or administrative suspension of activities for up to ninety days.

2. Sale or import into the territory of the Russian Federation of substandard medicinal products, or the sale or import into the territory of the Russian Federation of substandard medical devices, or illegal manufacturing, sale or import into the territory of the Russian Federation of unauthorized medicinal products, with the exception of the cases provided for in part 3 of this article, if these actions do not contain a criminal offense, -

shall incur an administrative fine on citizens in the amount of seventy thousand to one hundred thousand rubles; for officials - from one hundred thousand to six hundred thousand rubles; for individual entrepreneurs - from one hundred thousand to six hundred thousand rubles or administrative suspension of activities for up to ninety days; for legal persons - from one million to five million rubles or administrative suspension of activities for up to ninety days.

3. Sale of falsified, counterfeit, substandard or unauthorized medicinal products or falsified dietary supplements, or the sale of falsified, counterfeit or substandard medical devices, committed using the mass media or information and telecommunication networks, including the Internet, if these actions do not contain a criminal offense, -

shall incur an administrative fine on citizens in the amount of seventy-five thousand to two hundred thousand rubles; for officials - from one hundred and fifty thousand to six hundred thousand rubles; for individual entrepreneurs - from one hundred and fifty thousand to six hundred thousand rubles or administrative suspension of activities for up to ninety days; for legal persons - from two million to six million rubles or administrative suspension of activities for up to ninety days.

Note. The actions provided for by part 2 or 3 of this article are not an administrative offense if the sale and (or) import of unauthorized medicinal products or medical devices is allowed in accordance with the legislation on the circulation of medicinal products and legislation in the field of health protection, and (or) these medicinal products or medical devices are not manufactured in the Russian Federation, and (or) the indicated medicinal products or medical devices are recommended for use by the World Health Organization. "

Legal persons are also subject to liability under Article 6.34 of the Code of Administrative Offenses of the Russian Federation for “untimely entry of data into the system for monitoring the movement of medicinal products for human use or entering inaccurate data into it” (punishment is an administrative fine in the amount of fifty thousand to one hundred thousand rubles).

Question 9: Sanctions and measures

a. Please indicate which sanctions internal law provides for the criminal offences established in accordance with the Convention with regard to both natural and legal persons. Please specify whether the sanctions are criminal, civil and/or administrative sanctions (**Article 12, Explanatory Report, paras. 84-91**).

The type and amount of punishment for crimes related to falsification of medical products is indicated above in the answers to question 1.

When imposing a punishment, the court takes into account the nature and degree of social danger of the crime and the personality of the culprit, including the circumstances mitigating and aggravating the punishment, as well as the impact of the imposed punishment on the correction of the convicted person and on the living conditions of his family. One of the fundamental principles of criminal legislation states that punishment and other measures of a criminal-legal nature applied to a person who committed a crime must be fair, that is, correspond to the nature and degree of social danger of the crime, the circumstances of its commission and the personality of the culprit (Article 6 of the Criminal Code of the Russian Federation).

b. Which legislative or other measures have been taken to provide for the possibility of taking into account final sentences passed by another Party in relation to the offences established in accordance with the Convention? Please provide details and describe any good practice resulting from the taking of these measures (**Article 14, Explanatory Report, paras. 100-105**).

The commission of an intentional crime by a person with a criminal record for a previously committed intentional crime constitutes a relapse. The rules for recognizing the recurrence of crimes and its type are established by Article 18 of the Criminal Code of the Russian Federation:

«Article 18. Repeated crimes

1. A repeated crime is the commission of an intentional crime by a person who has a previous conviction for an intentional crime.

2. Repeated crime is considered dangerous:

a) when a person commits a grave crime for which he is sentenced to real imprisonment, if earlier this person was convicted two or more times for an intentional medium-gravity crime to imprisonment;

b) when a person commits a grave crime, if he was previously convicted of a grave or especially grave crime to real imprisonment.

3. The repeated crime is recognized as especially dangerous:

a) when a person commits a grave crime for which he is sentenced to real imprisonment, if earlier this person was twice convicted of a grave crime to real imprisonment;

b) when a person commits an especially grave crime, if previously he was twice convicted of a grave crime or previously convicted of an especially grave crime.

4. When recognizing the repeated crime are not taken into account:

a) convictions for intentional crimes of little gravity;

b) convictions for crimes committed by a person under the age of eighteen;

c) convictions for crimes for which the conviction was conditional or for which a suspension of execution of the sentence was granted, if the conditional sentence or suspension of the execution of the sentence was not canceled and the person was not sent to serve the sentence in places of imprisonment, as well as convictions removed or canceled in the manner established by Article 86 of the Code.

5. The repeated crime entails a more severe punishment on the basis and within the limits provided for by this Code, as well as other consequences provided for by the legislation of the Russian Federation».

In Russian criminal law, the repeated crime is an aggravating circumstance (Article 63, p. 1, lett. "a" of the Criminal Code of the Russian Federation), in the presence of which the punishment is imposed according to certain rules with the restriction of the minimum possible punishment (Article 68, p.2 of the Criminal Code of the Russian Federation). The available opportunity to impose punishment below this limit (Article 68, p.3 of the Criminal Code of the Russian Federation) is a manifestation of the principle of the humanity of the state, individualization and fairness of punishment and does not indicate that the legislator has not taken measures to impose a more severe punishment in case of a repeated crime. These are certain preferences for the culprit, which the state is ready to provide to a person, taking into account his positive behavior prior to sentencing (for example, in connection with rendering assistance to the victim, compensation for harm), special services to the country and society, and so on.

It should be borne in mind that in the Russian jurisdiction only conviction in the Russian Federation matters for the recognition of a repeated crime.

With regard to the international repeated crime, we note the following. As pointed out by the Constitutional Court of the Russian Federation, a criminal record is a legal status of a person, conditioned by the fact of conviction and imposition of punishment for a committed crime by court verdict and entailing

legal consequences established by criminal legislation when this person commits a crime again; a person's outstanding or unexpunged conviction gives rise to special public-law relations formed on the basis of criminal law regulation with the state, which, when this person commits new crimes, serve as the basis for assessing his personality and the crimes committed by him as having increased social danger and therefore presuppose application of stricter criminal measures to him. In other words, the mechanism of criminal proceedings by its nature is an individual legal relationship between a specific individual and a specific sovereign state - the Russian Federation. It is impossible to speak about the possibility of recognizing an international repeated crime in our jurisdiction without thorough scientific research, analysis of national and international legislation, and an assessment from the point of view of the constitutionality of such a provision. At the same time, each of the countries of the Commonwealth of Independent States, by virtue of Article 76 of the Convention on Legal Assistance and Legal Relations in Civil, Family and Criminal Cases of 22.01.1993 «when investigating crimes and considering criminal cases by courts, takes into account the mitigating and aggravating circumstances provided for by the legislation of the Contracting Parties, regardless of the territory of which Contracting Party they arise».

In addition, when imposing a sentence, the court takes into account the data on the identity of the culprit. This wording assumes an assessment of any information that characterizes the guilty person, which is available to the court when sentencing. Information about the conviction of the defendant in another state is more negative. Of course, such information, if available, can be perceived by the judge and affect his subjective opinion about the fairness and amount of punishment. However, they cannot be an aggravating circumstance, the list of which is exhaustive (Article 63 of the Criminal Code of the Russian Federation).

Individuals who have committed a crime under article 238^{1} of the Criminal Code of the Russian Federation, punishable by forced labor for a term of three to five years with deprivation of the right to occupy certain positions or engage in certain activities for a term up to three years or without such, or by imprisonment for a term of three to five years with a fine in the amount from five hundred thousand to two million rubles or the salary or other income of a convict for a period from six months to two years or without such and with deprivation of the right to occupy certain positions or engage in certain activities for a term up to three years or without such deprivation.

These acts committed using the mass media or information and telecommunications networks, including the Internet, are punishable by forced

labor for a term of four to five years, with or without deprivation of the right to hold certain positions or engage in certain activities for a term of two to three years or by imprisonment for a term from four to six years with a fine in the amount from seven hundred and fifty thousand to two million five hundred thousand rubles or the salary or other income of a convict for a period from one year to two years or without such and with deprivation of the right to occupy certain positions or engage in certain activities for a term up to four years or without that (Article 238^1, p.1.1 of the Criminal Code of the Russian Federation).

The specified acts committed by a group of persons by prior agreement or an organized group, as well as those that caused serious harm to health or death by negligence, are punishable by imprisonment for a term of five to eight years with a fine of one million to three million rubles or in the amount of the salary or other income of the convicted person for a period from one to three years or without it and with deprivation of the right to hold certain positions or engage in certain activities for a period of up to five years or without it (Article 238^1, p.2 of the Criminal Code of the Russian Federation).

These acts, which negligently entailed the death of two or more persons, are punishable by imprisonment for a term of eight to twelve years with a fine in the amount of two million to five million rubles or in the amount of the convicted person's wages or other income for a period of two to five years, or without it and with the deprivation of the right to hold certain positions or engage in certain activities for up to ten years or without it (Article 238^1, p.3 of the Criminal Code of the Russian Federation).

For manufacture use or sale, or knowingly using falsified documents for medicinal products or medical devices under Article 327^2, p.1 of the Criminal Code, a physical person shall be punished by a fine in the amount from five hundred thousand to one million rubles or the salary or other income of a convict for a period from one year to two years, or compulsory works for a term up to three years, or imprisonment for the same term.

Manufacturing for the purpose of using or selling or using knowingly counterfeit primary packaging and (or) secondary (consumer) packaging of a medicinal product is punishable by a fine in the amount of five hundred thousand to one million rubles or in the amount of the convicted person's wages or other income for a period of one to two years or forced labor for up to three years, or imprisonment for the same period (Article 327^2, p.2 of the Criminal Code of the Russian Federation).

These acts committed by an organized group are punishable by imprisonment for a term of five to ten years with deprivation of the right to hold

certain positions or engage in certain activities for a term of up to three years (Article 327^2, p.3 of the Criminal Code of the Russian Federation).

Legal persons for administrative offenses under part 1 of article 6.33 of the administrative Code of the Russian Federation are liable in the form of an administrative fine from one million to five million rubles or administrative suspension of activity for up to ninety days.

The sale or import into the territory of the Russian Federation of substandard medicinal products, or the sale or import into the territory of the Russian Federation of substandard medical devices, or the illegal manufacturing, sale or import into the territory of the Russian Federation of unauthorized medicinal products entails the imposition of an administrative fine on legal persons from one million to five million rubles or administrative suspension of activities for up to ninety days (Article 6.33, p.2 of the Administrative Code of the Russian Federation).

The following exception is provided from this rule – sale of falsified, counterfeit, substandard or unauthorized medicinal products or falsified dietary supplements or sale of falsified, counterfeit or substandard medical products made using mass media or information and telecommunications networks, including the Internet, entail the imposition of an administrative fine on legal persons from two million to six million rubles or administrative suspension of activities for up to ninety days (Article 6.33, p.3 of the administrative Code of the Russian Federation).

Question 10: Aggravating Circumstances

Please indicate which of the circumstances referred to in **Article 13**, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of internal law, be taken into consideration in your legal system as aggravating circumstances in the determination of the sanctions in relation to the offences established in accordance with this Convention (**Explanatory Report, paras. 92-99**).

Under Russian criminal law, all the circumstances specified in Article 13 of the Convention can be considered as aggravating punishment.

An exhaustive list of circumstances that aggravate the punishment provided for in Article 63 of the Criminal Code of the Russian Federation. It includes:

a) repeated crime;

b) grave consequences of a crime;

c) commission of a crime as part of a group of persons, a group of persons by prior conspiracy, an organized group or a criminal community (criminal organization);

d) a particularly active role in the commission of a crime;

e) involvement in the commission of a crime of persons who suffer from severe mental disorders or are in a state of intoxication, as well as persons who have not reached the age from which criminal liability begins;

f) commission of a crime based on political, ideological, racial, national or religious hatred or enmity, or on the basis of hatred or enmity against any social group;

g.1) commission of a crime out of revenge for the lawful actions of others, as well as with the aim of concealing another crime or facilitating its commission;

h) commission of a crime against a person or his relatives in connection with the performance of this person's official activities or the fulfillment of a public duty;

i) commission of a crime against a woman, knowingly for the culprit who is in a state of pregnancy, as well as against a minor, other defenseless or helpless person, or a person who is dependent on the culprit;

j) commission of a crime with special cruelty, sadism, abuse, and also torment for the victim;

k) commission of a crime with the use of weapons, military supplies, explosives, explosive or imitating devices, specially manufactured technical means, narcotic drugs, psychotropic, highly potent, toxic and radioactive substances, medicinal and other chemical-pharmacological preparations, as well as with the use of physical or mental coerce;

l) commission of a crime in a state of emergency, natural or other public disaster, as well as during mass riots, armed conflict or military operations;

m) commission of a crime using the confidence placed in the culprit by virtue of his official position or contract;

n) commission of a crime using a uniform or documents of a government official;

o) intentional crime committed by an employee of the internal affairs authority;

p) the commission of a crime against a minor by a parent or other person who is legally responsible for the upbringing of a minor, as well as by a teacher or other employee of an educational organization, a medical organization, an organization providing social services, or another organization obliged to supervise a minor;

q) committing a crime to promote, justify and support terrorism.

This list is not subject to broad interpretation..

In addition, a number of circumstances are provided for by articles of the Special Part of the Criminal Code of the Russian Federation as a sign of a crime, in particular, commission using the media or information and telecommunication networks, including the Internet (part 1.1 of article $238^1$of the Criminal Code of the Russian Federation), causing, as a result of the commission of a crime by negligence, serious harm to health or death of a person (Article 238^1, p.2, lett. "b" of the Criminal Code of the Russian Federation).

As aggravating circumstances when imposing sanctions in connection with offenses recognized as such in accordance with the Convention under consideration, the following are recognized, not specified in Article 238^1 of the Criminal Code of the Russian Federation:

the offender has previously been convicted of committing offenses of a similar nature (Article 63, p.1, lett. "a" of the Criminal Code of the Russian Federation);

the offense was committed by persons who abused the trust placed in them in connection with their professional activities (Article 63, p.1, lett. "m" of the Criminal Code of the Russian Federation).

Question 11: Investigation and criminal measures

a. Which legislative or other measures have been taken to ensure that investigations or prosecutions of offences established in accordance with the Convention shall not be subordinate to a complaint and that the proceedings may continue even if the victim has withdrawn his or her statement? (**Article 15, Explanatory Report, para. 106**).

In accordance with the provisions of Article 20 of the Criminal Procedure Code of the Russian Federation, criminal cases on crimes provided for by Articles 238^1, 327^2 of the Criminal Code of the Russian Federation refer to cases of public prosecution, and therefore are initiated regardless of the presence of a victim's statement and cannot be terminated in connection with the withdrawal of the statement by the victim.

b. Please indicate the persons, units or services or other formalised or agreed arrangements in charge of criminal investigations in the field of MEDICRIME Convention. Please indicate how specialisation in this field is achieved and how resources are secured for it/them (**Article 16, para. 1, Explanatory Report, paras. 107-110**).

The detection, prevention and suppression of crimes of this category are within the competence of the Ministry of Internal Affairs of Russia. A preliminary investigation in accordance with Article 151 of the Criminal Procedure Code of the Russian Federation is carried out by investigators of the Investigative Committee of the Russian Federation.

For information on employee training see the answer to question 13c.

c. Please describe under which circumstances carrying out financial investigations, the use of covert operations, of controlled delivery and of other special investigative techniques by authorities is allowed in relation to the investigation of the offences established in accordance with the Convention (**Article 16, para. 2**).

Federal Law of 12.08.1995 N 144-FZ "On investigative activities" defines the content of investigative activities carried out on the territory of the Russian Federation, and establishes a system of guarantees of legality during investigative activities. In accordance with Article 3, the investigative activity is based on the constitutional principles of legality, respect and observance of human and civil rights and freedoms, as well as on the principles of conspiracy, a combination of public and private methods and means.

Article 23, p. 2, Constitution of the Russian Federation: *"Everyone has the right to privacy of correspondence, telephone conversations, postal, telegraphic and other messages. Limitation of this right is allowed only on the basis of a court decision."*

In order to verify compliance with the prohibition on the sale of counterfeit medical devices, substandard medical devices and counterfeit medical devices (Article 95 of the Federal Law of 21.11.2011 N 323-FZ "On the basics of health protection of

citizens in the Russian Federation"), as well as the prohibition of the sale of falsified medicinal products, substandard medicinal products and counterfeit medicinal products (Article 9 of the Federal Law of 12.04.2010 N 61-FZ "On the circulation of medicinal products") Roszdravnadzor conducts test purchases in accordance with the procedure established by the Federal Law of 26.12.2008 N 294-FZ "On protection of the rights of legal persons and individual entrepreneurs in the implementation of state control (supervision) and municipal control".

Question 12: Measures of protection for the victim

a. Please describe the measures taken to (**Article 19**):
   - ensure that victims have access to information relevant to their case and which is necessary for the protection of their health;
   - assist victims in their physical, psychological and social recovery;
   - provide for the right of victims to compensation from the culprits.

b. Please describe the measures taken to inform victims of their rights, the services at their disposal, the follow-up given to their complaint, the charges, the general progress of the investigation or proceedings, and their role as well as the outcome of their cases (**Article 20, para. 1, letter (a) and para. 2**).

c. Please also indicate which measures have been taken to enable the victim to be heard, to supply evidence and to choose the means of having his/her views, needs and concerns presented, directly or through an intermediary, and considered (**Article 20, para. 1, letter (b)**);

d. What kind of support services are provided to victims so that their rights and interests are duly presented and taken into account? (**Article 20, para. 1, letter (c)**)

e. Please describe the measures taken to provide the safety of the victims, their families and witnesses from intimidation and retaliation (**Article 20, para. 1, letter (d)**);

f. Please specify under which conditions victims of the offences established according to the Convention have access to legal aid provided free of charge (**Article 20, para. 3**).

g. Which legislative or other measures have been taken to ensure that victims of an offence established in accordance with the Convention in the territory of a Party other than the one where they reside may make a complaint before the competent authorities of their state of residence? (**Article 20, para. 4, Explanatory Report, para. 128**).

h. Please describe how your internal law allows for groups, foundations, associations or governmental or non-governmental organisations assisting and/or supporting victims to participate in legal proceedings (for example, as third parties) (**Article 20, para. 5**). Please specify under which conditions, if so required

Please note that the answers are combined.

In accordance with part 1 of Article 42 of the Criminal Procedure Code of the Russian Federation, the victim is an individual to whom the crime has caused physical, property, moral harm, as well as a legal person in the case of damage to its property and business reputation by the crime.

According to Chapter 6 of the Criminal Procedure Code of the Russian Federation, the victim is a participant in criminal proceedings on the part of the prosecution.

The decision on recognition as a victim is taken immediately from the moment of initiation of a criminal case and is formalized by a decision of an inquiry officer, investigator, judge or a court ruling. If at the time of the initiation of the criminal case there is no information about the person who was harmed by the crime, the decision on recognition as a victim shall be made immediately after receiving the information about this person.

In criminal cases of crimes, the consequence of which was the death of a person, the rights of the victim are transferred to one of his close relatives and (or) close persons, and in their absence or the impossibility of their participation in criminal proceedings - to one of the relatives.

When a person is recognized as a victim, the rights and obligations provided for by the Criminal Procedure Code of the Russian Federation are explained to him. At the judicial stage of criminal proceedings, the duty to explain to the victim his rights and responsibility in court proceedings rests with the court (Article 268 of the Criminal Procedure Code).

The victim, his legal representative and (or) representative may participate in the criminal prosecution of the accused, and in criminal cases of private prosecution - to bring forward and support charges in the prescribed manner.

Also, the victim has the right to:

1) know about the charge brought against the accused;

2) give evidence;

3) refuse to testify against himself, her husband (his wife) and other close relatives, the circle of which is determined by Article 5, p. 4 of the Criminal Procedure Code of the Russian Federation. If the victim agrees to testify, he must be warned that his testimony can be used as evidence in a criminal case, including in the event of his subsequent refusal from this testimony;

4) present the evidences;

5) submit requests and objections;

6) testify in his native language or in the language he speaks;

7) use the help of an interpreter free of charge;

8) have a representative;

9) participate, with the permission of the investigator or the inquiry officer, in investigative actions carried out at his request or at the request of his representative;

10) get acquainted with the protocols of investigative actions carried out with his participation, and submit comments on them;

11) get acquainted with the decision on the appointment of a forensic examination and the expert's opinion;

12) get acquainted, at the end of the preliminary investigation, including in the case of termination of the criminal case, with all the materials of the criminal case, write out any information from the criminal case and in any volume, make copies of the materials of the criminal case, including using technical means. If several victims are involved in a criminal case, each of them has the right to get acquainted with the materials of the criminal case that relate to the harm caused to this victim;

13) receive copies of decisions on the initiation of a criminal case, on recognizing him as a victim, on the refusal to elect a preventive measure against the accused in the form of detention, on the termination of the criminal case, on the suspension of criminal proceedings, on the direction of the criminal case according to the jurisdiction, on the appointment of a preliminary hearing, a court session, receive copies of the verdict of the first instance court, decisions of the courts of appeal and cassation The victim, upon request, has the right to receive copies of other procedural documents affecting his interests;

14) participate in the judicial proceeding of a criminal case in the courts of the first, second, cassation and supervisory instances, to object to the ruling of a sentence without a trial in a general manner, as well as in the cases provided for by the Criminal Procedure Code of the Russian Federation, to participate in a court hearing when the court considers the issues related to the execution of the sentence;

15) speak in judicial pleadings;

16) support the accusation;

17) get acquainted with the protocol and audio recording of the court session and submit comments on them;

18) lodge complaints about the actions (inaction) and decisions of the inquiry officer, the head of the inquiry unit, the head of the inquiry body, inquiry body, investigator, prosecutor and court;

19) appeal against the sentence, court decision, court ruling;

20) know about the complaints and representations brought in in the criminal case and to submit objections to them;

21) seek the application of security measures in accordance with part three of Article 11 of the Criminal Procedure Code of the Russian Federation;

21.1) on the basis of a court decision, a court ruling, adopted at the request of the victim, his legal representative, representative, filed before the end of the debate of the parties, to receive information about the arrival of the person sentenced to imprisonment at the place of serving the sentence, including when moving from one correctional institution to another, about the convict's departure from the institution executing a sentence of imprisonment, about the time of the convict's release from places of imprisonment, as well as being notified of the court's consideration of issues related to the execution of the sentence about the release of the convicted person from punishment, about the postponement of the execution of the sentence or about the replacement of the convicted person with unserved parts of punishment with a milder type of punishment;

22) exercise other powers provided for by the Criminal Procedure Code of the Russian Federation.

The victim is provided with compensation for property damage caused by the crime, as well as expenses incurred in connection with his participation in the preliminary investigation and in court, including expenses for a representative.

At the claim of the victim for compensation in monetary terms for the moral damage caused to him, the amount of compensation is determined by the court when considering a criminal case or in civil proceedings (Article 42 of the Criminal Procedure Code of the Russian Federation).

Russian procedural legislation provides for a mechanism that allows participants in criminal proceedings to exercise their rights indirectly.

Any person involved in criminal proceedings, incl. the victim has the right to use the services of a representative. In accordance with Article 45 of the Criminal Procedure Code of the Russian Federation, lawyers may be representatives of the victim. As a representative of the victim, one of the close relatives of the victim or another person for whose admission the victim is applying may also be admitted. To protect the rights and legitimate interests of victims who are minors or, by their physical or mental state, are deprived of the opportunity to independently defend their rights and legitimate interests, their legal representatives or representatives are involved in mandatory participation in a criminal case. At the request of the legal representative of a minor victim under the age of sixteen, in respect of whom a crime against the sexual

inviolability of a minor has been committed, the participation of a lawyer as a representative of such a victim is ensured by an inquiry officer, an investigator or a court. In this case, the costs of the lawyer's labor are compensated by the federal budget. The legal representatives and representatives of the victim have the same procedural rights as the persons they represent. Personal participation in a criminal case of a victim, civil plaintiff or private prosecutor does not deprive him of the right to have a representative in this criminal case.

During the course of the interrogation, at the initiative of the investigator or at the request of the person being interrogated, photographing, audio and (or) video recording, filming may be carried out, the materials of which are stored in the criminal case and at the end of the preliminary investigation are sealed (part 4 of article 189 of the Criminal Procedure Code of the Russian Federation). When the court is considering a criminal case, if the victim or witness fails to appear at the court session, the court has the right to decide on the announcement of the testimony given by them earlier and on the reproduction of a video recording or filming of investigative actions carried out with their participation, including cases of a serious illness preventing the appearance of the victim, witness to the court (Article 281 of the Criminal Procedure Code of the Russian Federation).

Federal Law N 220-FZ of 23.06.2016 "On amendments to certain legislative acts of the Russian Federation in the application of electronic documents in the activities of judicial authorities" implemented the ability to submit applications to the court in electronic form. The procedure for submitting such documents is enshrined in article 474.1 of the Criminal Procedure Code of the Russian Federation:

«1. A request, application, complaint, submission can be filed with the court in the manner and terms established by the Criminal Procedure Code of the Russian Federation, in the form of an electronic document signed by the person who sent such a document with an electronic signature in accordance with the legislation of the Russian Federation, by filling out the form posted on the official the site of the court in the information and telecommunication network "Internet". Materials attached to a request, application, complaint, submission are also submitted in the form of electronic documents. Electronic documents produced by other persons, bodies, organizations in free form or in the form established for these documents by the legislation of the Russian Federation must be signed by them with an electronic signature in accordance with the requirements of the legislation of the Russian Federation.

2. A court decision, with the exception of a decision containing information constituting a secret protected by federal law, affecting the security

of the state, the rights and legal interests of minors, decisions on cases of crimes against sexual inviolability and sexual freedom of the individual, may be made in the form of an electronic document, which signed by the judge with an enhanced qualified electronic signature. If the court decision is made by the court collegially, it is signed by all the judges who participated in the consideration of the case, reinforced with a qualified electronic signature. When preparing a court decision in the form of an electronic document, a copy of the court decision is additionally made on paper.

3. A copy of the court decision, made in the form of an electronic document, certified by an enhanced qualified electronic signature, at the request or with the consent of a participant in criminal proceedings, may be sent to him using the information and telecommunications network "Internet"».

Federal Law N 262-FZ of 22.12.2008 "On ensuring access to information on the activities of courts in the Russian Federation" provides for a number of measures in order to achieve a high level of publicity and transparency of justice:

- disclosure of information about the judicial system and courts, as well as basic information about judges, senior officials of the court apparatus;
- providing full information on the time and procedure for the work of courts, on the movement of cases and applications in court, including information on the time and place of their consideration, postponement and suspension;
- creation of a system guaranteeing the general availability of judicial acts (sentences, decisions, etc.).

All this information available from the public domain on the Internet. A serious step is the introduction of a procedure for publishing sentences and other court decisions on the Internet. Participants in legal proceedings can, in free access, get acquainted with the decisions of higher courts, track the progress of the case, study judicial practice, etc.

The Russian legal system has a mechanism to prevent re-victimization.

Federal Law N 119-FZ of 20.08.2004 "On state protection of victims, witnesses and other participants in criminal proceedings" laid the foundations for a system of state protection of victims, witnesses and other participants in criminal proceedings. The law establishes the principles of implementation and types of state protection, including security and social support measures, defines the bodies providing state protection, and the procedure for applying the corresponding measures.

The Criminal Procedure Code of the Russian Federation also contains norms that ensure the protection of victims of criminal offenses. In accordance with Article 11, p.3 of the Criminal Procedure Code of the Russian Federation, if there is sufficient evidence that the victim, witnesses or other participants in criminal proceedings, as well as their close relatives, relatives or close persons are threatened with murder, violence, destruction or damage to their property or other dangerous illegal acts, the court, prosecutor , the head of the investigative body, the investigator, the body of inquiry, the head of the body of inquiry, the head of the subdivision of inquiry and the interrogator shall, within the limits of their competence, take the security measures provided for by the legislation with respect to the said persons.

So, if necessary, to ensure the safety of the victim, his representative, their close relatives, relatives and close persons, the investigator (interrogator) has the right not to provide information about their identity in the protocol of the investigative action (interrogation) (Article 166, p.9 of the Criminal Procedure Code of the Russian Federation). In this case, the participant in the investigative action acts under a pseudonym. The investigator (interrogator) makes a decision on this and this document is placed in a sealed envelope, which is attached to the case. The resolution indicates the reasons for the decision to keep the information about the victim secret, indicates the pseudonym of the participant in the investigative action and provides a sample of his signature, which he will use in the protocols of investigative actions carried out with his participation.

Article 193, p.8 of the Criminal Procedure Code of the Russian Federation established the possibility of making identification in conditions that exclude the visual observation of the identifier by the identifiable. The current criminal procedure law does not exclude the possibility of using a photo or video image of an identifiable person for identification.

If there is a threat of violence, extortion and other criminal actions against the victim, witness or their close relatives, relatives, close persons, control and recording of telephone and other conversations is allowed upon a written application of these persons, and in the absence of such an application - on the basis of a court decision (Article 186, p.2 of the Criminal Procedure Code of the Russian Federation).

When considering the case by the court, additional security measures may be applied. The protection of the participants in the process in the courts, including the victims, is entrusted to the bailiffs, who act in accordance with Federal Law N 118-FZ of 21.07.1997 "On the enforcement agencies of the

Russian Federation." To repel attacks on participants in the process, bailiffs can use the special means and weapons they have in their arsenal.

Based on Article 241 of the Criminal Procedure Code of the Russian Federation, in the case when the consideration of criminal cases on crimes against sexual inviolability and sexual freedom of the individual may lead to the disclosure of information about the intimate aspects of the life of the victims, as well as to ensure the safety of the participants in the proceedings, their close relatives, relatives or close persons, it is possible to conduct a closed trial proceedings. The decision of the court to consider the case in closed court session is possible in relation to the entire trial or part of it.

If it is necessary to ensure the safety of the witness, his close relatives, relatives and close persons, the court, without disclosing the true data about the identity of the witness, has the right to interrogate him in conditions that exclude visual observation of the witness by other participants in the trial, about which the court issues a ruling or ruling (Article 278, p.5 of the Criminal Procedure Code of the Russian Federation).

In accordance with Article 29 of the Civil Procedure Code of the Russian Federation "Claims for compensation for harm caused by injury, other damage to health, or as a result of the death of the breadwinner, may also be brought by the plaintiff to the court at his place of residence or place of harm."

V. PREVENTION OF COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 13: Ensure quality and safety requirements of medical products, awareness raising and training

a. Which legislative or other measures have been taken to establish the quality, efficacy and safety requirements of medical products? (**Article 18 para. 1, Explanatory Report, para. 113**)

Relations arising in the sphere of public health protection in the Russian Federation are regulated by Federal law N 323-FZ of 21.11.2011 "On the basics of public health protection in the Russian Federation".

Federal law N 61-FZ of 12.04.2010 "On the circulation of medicinal products" regulates relations arising in connection with the circulation of medicines - development, preclinical trials, clinical trials, expertise, state registration, standardization and quality control, production, manufacture, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, release, sale, transfer, use, utilization of medicines, and also sets the priority of state regulation of the safety, quality and efficacy of medicines in circulation.

The functioning of the common market of medicinal products within the Eurasian economic Union is carried out in accordance with Article 30 of the Treaty on the Eurasian economic Union of 29.05.2014, the Agreement on common principles and rules of circulation of medicinal products within the Eurasian economic Union dated 23.12.2014, and in accordance with acts of the Eurasian economic Commission in the sphere of circulation of medicinal products.

The functioning of the common market of medical devices within the Eurasian economic Union is carried out in accordance with Article 31 of The Treaty on the Eurasian economic Union of 29.05.2014, the Agreement on common principles and rules for the circulation of medical devices (medical devices and medical equipment) within the Eurasian economic Union of 23.12.2014, as well as in accordance with the acts of the Eurasian economic Commission in the field of circulation of medical devices.

Article 7 of the Federal law of 12.04.2010 N 61-FZ "On circulation of medicinal products" provides for the development and publication of the state Pharmacopoeia, the publication of data about it in the Internet (https://www.regmed.ru/gf/State_Pharmacopoeia_XIV).

Article 9 of the Federal law of 12.04.2010 N 61-FZ "On circulation of medicinal products" provides for the selective control of quality of medicinal

products by processing information that must be provided by the subjects of circulation of medicinal products about series, batches of medicinal products coming into the civil circulation in the Russian Federation, and the sampling of medicinal products from subjects of circulation of medicinal products in order to test their compliance with the normative documentation.

Based on the results of quality control of medicines, a decision is made to stop circulation and destroy substandard medicines.

Article 52.1 of the Federal law of 12.04.2010 N 61-FZ "On circulation of medicinal products" defines the procedure for entering into civil circulation of medicinal products for human use including state control of first-time released and first-time manufactured medicinal products (with the exception of immunobiological medicinal products) in Federal state laboratories and batch state quality control of immunobiological medicinal products.

By decision of the Board of the Eurasian economic Commission N 119 dated 22.09.2015, the Concept of Harmonization of Pharmacopoeias of the member States of the Eurasian economic Union was approved. The decision of the Board of the Eurasian economic Commission N 100 of 11.08.2020 approved the Pharmacopoeia of the Eurasian economic Union, which will enter into force on March 1, 2021.

The Russian Federation has good pharmaceutical practices that are harmonized with international requirements and approved by relevant legal acts:

order of the Ministry of industry and trade of the Russian Federation of 14.06.2013 N 916 "On approval of the rules of good manufacturing practice";

order of the Ministry of health of the Russian Federation N 646n of 31.08.2016 "On approval of the rules of good practice of storage and transportation of medicines for human use»;

order of the Ministry of health of the Russian Federation N 647n dated 31.08.2016 "On approval of the rules of good pharmacy practice of medicines for human use»;

"GOST 33647-2015. Interstate standard. Principles of good laboratory practice (GLP). Terms and definitions" (put into effect by the order of Rosstandart of 18.11.2015 N 1868-St);

"GOST R ISO 14155-2014. National standard of the Russian Federation. Clinical trials. Good clinical practice" (approved and put into effect by the order of Rosstandart of 04.06.2014 N 497-St);

decision of the Council of the Eurasian economic Commission of 3.11.2016 N 87 "On approval of the Rules of good pharmacovigilance practice of the Eurasian economic Union".

State control over the circulation of medical devices includes:

a) conducting inspections of compliance by subjects of circulation of medical devices with the rules approved by the authorized Federal Executive authority in the field of circulation of medical devices;

b) issuing permits for the import of medical devices into the territory of the Russian Federation for the purpose of their state registration;

c) monitoring the safety of medical devices;

d) conducting control purchases in order to verify compliance with the ban on the sale of counterfeit medical devices, substandard medical devices and counterfeit medical devices (article 95 of Law N 323-FZ).

b. Which legislative or other measures have been taken to ensure the safe distribution of medical products? (**Article 18 p. 2**)

In accordance with Federal law N 323-FZ of 21.11.2011 "On the basics of public health protection in the Russian Federation" and government decree N 957 of 21.11.2011 "On licensing certain types of activities", Roszdravnadzor licenses pharmaceutical activities:

central office - licensing of pharmaceutical activities in terms of activities carried out by organizations that wholesale medicines for human use;

territorial bodies of Roszdravnadzor of the subjects of the Russian Federation - licensing of pharmaceutical activities in terms of activities carried out by pharmacy organizations subordinate to Federal executive authorities and state Academies of Sciences.

In addition, decree of the Government of the Russian Federation N 1567-R of 23.09.2010 gives Roszdravnadzor the authority to issue a certificate for the right to import (export) narcotic drugs, psychotropic substances and their precursors.

In terms of registration of import/export of narcotic drugs, psychotropic substances and their precursors, the rules established by the Regulation on the procedure for import into the customs territory, export from the customs territory and transit through the customs territory of the Customs Union of narcotic drugs, psychotropic substances and their precursors, which was approved by The decision of the Board of the Eurasian economic Commission of 21.04.2015 N 30 "On non-tariff regulation measures", apply.

The decision Of the Board of the Eurasian economic Commission N 45 of 16.05.2012 applies to registration of import/export of highly potent substances that are not precursors of narcotic drugs and psychotropic substances.

Federal law N 462-FZ of 27.12.2019 "On amendments to the Federal law "On the circulation of medicinal products" set the deadline for the introduction of mandatory labeling of medicinal products for human use – 01.07.2020.

In accordance with part 4 of article 67 of the Federal law of 12.04.2010 N 61-FZ "On circulation of medicinal products", for the purpose of identifying packages of medicinal products for human use, manufacturers of medicinal products apply identification means to the packaging of medicinal products for human use.

In accordance with part 7 of article 67 of the Federal law of 12.04.2010 N 61-FZ "On circulation of medicinal products", legal persons and individual entrepreneurs engaged in the manufacturing, storage, importation into the Russian Federation, release, sale, transfer, use and destruction of medicines for huyman use, ensure that information about medicines for human use is entered into the system for monitoring the movement of medicines for human use. Entering information about medicinal products into the Federal state information system for monitoring the movement of medicinal products is a mandatory licensing requirement (decree Of the Government of the Russian Federation N 688 of 15.05.2020 amended p. 5 of the Regulations on licensing of medical activities approved by decree of the Government of the Russian Federation N 291 of 16.04.2012).

Control over the circulation of medical devices on the territory of the Russian Federation means control over technical tests, toxicological studies, clinical trials, efficacy, safety, production, manufacture, sale, storage, transportation, import into the territory of the Russian Federation, export from the territory of the Russian Federation of medical devices, their installation, adjustment, use, operation, including maintenance, repair, disposal or destruction. The regulation on state control over the circulation of medical devices was approved by decree of the Government of the Russian Federation N 970 of 25.09.2012.

c. Which measures have been taken to provide for (**Article 18 para. 3 letters a and c, Explanatory Report, para. 114**):

- training of healthcare professionals, providers, law-enforcement (including police and customs authorities), as well as other relevant authorities and civil society?

In accordance with the Federal law of 27.07.2004 N 79-FZ "On the state civil service of the Russian Federation", professional development of employees

of these departments is aimed at maintaining and improving the level of qualification required for the proper performance of official duties, and includes additional professional education and other professional development activities. Professional development of a civil servant is carried out during the entire period of civil service.

Qualification requirements for professional knowledge and skills necessary for the performance of official duties are established by Article 62 of Federal Law N 79-FZ of 27.07.2004 "On the state civil service of the Russian Federation". Qualification requirements are provided for further training received by civil servants at least once every three years. In addition, a civil servant can also receive additional professional education both in Russia and abroad. Additional professional education received by a civil servant is confirmed by a qualification certificate, and information about it is entered in the employee's personal file. Professional requirements are defined in the job description.

Control of the acquired skills, knowledge and competencies of employees, was approved by article 48 "Certification of civil servants" of the Federal law of 27.07.2004 N 79-FZ "On the state civil service of the Russian Federation". Certification of a civil servant is carried out once every three years.

In accordance with the order of the Ministry of internal affairs of Russia of 05.05.2018 N 275 "On approval of the Procedure for organization of training staff to fill positions in internal affairs authorities of the Russian Federation" Ministry of internal affairs of Russia carries out its activities in the field of personnel training through the departments of the Central apparatus of the Ministry of internal affairs of Russia, territorial bodies of the Ministry of internal affairs of Russia, educational, scientific, and medical (including sanatorium-resort) organization of the system of Ministry of internal affairs of Russia, the Ministry's district offices, the logistics system of the Ministry of internal affairs of Russia, culture organizations, physical culture and sports organizations, editorial offices of print and electronic mass media, as well as other organizations and divisions created to perform tasks and exercise powers assigned to the internal affairs bodies of the Russian Federation.

Order of the Federal service for surveillance in health care N 5787 of 14.08.2014 approved the qualification requirements for professional knowledge and skills required for the performance of official duties by Federal state civil servants of the Central office and territorial bodies of the Federal service for surveillance in health care. Each state civil servant has an individual professional development plan for a state civil servant, developed for three years.

The issues of countering the circulation of counterfeit medical products are covered in the framework of the annual all - Russian conference "State regulation in the sphere of circulation of medicinal products and medical devices - "PharmMedObrascheniye 2020" organized by Roszdravnadzor. The conference traditionally brings together specialists in the medical and pharmaceutical industries, representatives of Federal and regional legislative and executive authorities of the Russian Federation, relevant foreign regulatory authorities, research and public organizations, professional associations, wholesale and retail organizations and manufacturers of medical products.

- the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?

In order to verify compliance with the ban on the sale of counterfeit medical devices, substandard medical devices and counterfeit medical devices (article 95 of the Federal law of 21.11.2011 N 323-FZ "On the basics of public health protection in the Russian Federation"), as well as the ban on the sale of counterfeit medicinal products, substandard medicinal products and counterfeit medicinal products (Article 9 of Federal law N 61-FZ of 12.04.2010 "On circulation of medicinal products"), Federal law N 294-FZ of 26.12.2008 "On protection of the rights of legal persons and individual entrepreneurs during the exercise of state control (supervision) and municipal control" Roszdravnadzor exercises state control (supervision) in the sphere of circulation of medicinal products and medical devices, which includes:
- conducting inspections of subjects of medical products circulation;
- sampling of medical products as part of verification measures and selective control;
- conducting control purchases;
- examination of the quality of selected samples in state laboratories;
- making decisions based on the results of tests and expertise on the further circulation of medical products.

In accordance with article 59 of Federal law N 61-FZ of 12.04.2010 "On circulation of medicinal products" substandard medicinal products and falsified medicinal products are subject to withdrawal from circulation and destruction. Requirements for the destruction of substandard, falsified and counterfeit medicinal products are defined by decree of the Government of the Russian Federation N 674 of 03.09.2010 "On approval of the rules for the destruction of

substandard medicinal products, falsified medicinal products and counterfeit medicinal products".

In accordance with article 38 of Federal law N 323-FZ of 21.11.2011 "On the basics of public health protection in the Russian Federation", falsified medical devices and substandard medical devices are subject to seizure and subsequent destruction or export from the territory of the Russian Federation, and counterfeit medical devices are subject to seizure and subsequent destruction. Falsified medical devices and substandard medical devices are exported from the territory of the Russian Federation at the expense of the person who imported them into the territory of the Russian Federation. The procedure for destruction of falsified medical devices, substandard medical devices and counterfeit medical devices is established by the Decree of the Russian Government of 12.12.2015 N 1360 "On separate questions of counteraction to trafficking of falsified, substandard and counterfeit medical devices".

Order of Roszdravnadzor N 5527 of 29.06.2020 approved criteria for evaluating information in Internet resources that can lead to the blocking of sites and their inclusion in the register of prohibited sites. Among the criteria are:
availability of offer for retail sale of falsified, substandard, counterfeit medicinal products for human use;
availability of offer for the retail trade of unauthorized medicinal products;
availability of offer for remote retail sale of prescription drugs;
availability of offer for remote retail sale of narcotic and psychotropic medicinal products;
etc.

d. Which policies or strategies have been implemented to promote or conduct awareness-raising campaigns targeted at the general public where the focus is directed especially towards the risks and realities of the counterfeiting of medical products and similar crimes involving threats to public health? Please describe the material used for the campaign/programme and its dissemination. If possible, please provide an assessment of the impact of the campaign/programme. If there are currently plans for launching a (new) campaign or programme, please provide details (**Article 18, para. 3 letter b**);

Order of the Government of the Russian Federation of 05.12.2016 N 2592-R approved the Strategy for combating illegal trafficking of industrial products in the Russian Federation for the period up to 2020 and the planned period up to 2025. The pharmaceutical and medical industries have been

identified as priorities for monitoring and taking measures to counteract illicit trafficking in industrial products. One of the main tasks to achieve this goal is to create an intolerant attitude of citizens to the consumption of industrial products that are in illegal circulation.

The formation of an intolerant attitude to the consumption of industrial products that are in illegal circulation provides for:

development and implementation of programs to improve the level of literacy of the population in the field of determining the legality of industrial products;

formation and implementation of an information campaign to combat industrial products that are in illegal circulation;

implementation and support of state systems of marking with quality marks of Russian industrial products, marks of belonging to goods produced in the member States of the Eurasian economic Union, protection of relevant marks;

development of electronic services for citizens that allow them to check the legality of industrial products and respond by filing complaints against unscrupulous market participants.

In parallel with the introduction of a system for monitoring the movement of medicinal products and identifying packages of medicinal products in order to combat their falsification (see the answer to question 3b), a mobile application has been developed that allows consumers to verify the authenticity of a medicinal product by reading the marking code at the time of purchase.