



MEDICRIME COMMITTEE

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211)

Questionnaire for the 1st thematic monitoring round:

The protection of public health through the MEDICRIME Convention in times of pandemics

As adopted by the MEDICRIME Committee on 27 May 2021

Replies should be addressed to the MEDICRIME Committee Secretariat

medicrime@coe.int

Introduction

1. The [Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health](#) (hereinafter “the MEDICRIME Convention” or “the Convention”), which entered into force on 28 October 2011, requires the criminalisation of offences set out in the Convention in Articles 5-8. It sets out that states, in Europe and beyond, shall adopt specific legislation to prevent and combat threats to public health by criminalising certain acts, protecting the rights of victims of the offences established under the Convention, and promoting national and international co-operation.
2. The Committee of the Parties to the Convention (also known as the “MEDICRIME Committee”), established to monitor whether Parties effectively implement the Convention (Rule 25 of the Committee’s Rules of Procedure), decided that:

“3. The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee.”

3. As available data show that offences involving medical products committed during a pandemic target critical funding through fraudulent scams, counterfeiting of vital protective personal equipment and critical medical devices to save lives and to detect the presence of the disease, and attacks on critical infrastructure in the fight against the disease, the MEDICRIME Committee decided that the first monitoring round would focus on “The protection of public health through the MEDICRIME Convention in times of pandemics”.¹
4. On 27 May 2021, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to offences involving medical products and similar crimes involving threats to public health and related to a pandemic. The replies to the questionnaire will be assessed against the related background information provided by the Parties when answering the “General Overview” questionnaire on the implementation of the MEDICRIME Convention (hereinafter “Country Profile Questionnaire” or “CPQ”) and any other relevant information from reliable sources.

¹ Committee of the Parties of the MEDICRIME Convention, *List of decisions*, 3rd Plenary meeting (1-3 December 2020), T-MEDICRIME-(2020) LD, paragraph 4.5.

5. It is recalled that, in accordance with Rule 26 of the Committee's Rules of Procedure:

"(...) 2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".

3. Parties shall co-ordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The replies to the questionnaires shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

4. The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.

5. The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."

PRELIMINARY REMARKS

6. As in the [country profile questionnaire](#), the provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without automatically following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.
7. This thematic questionnaire does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. It focuses only on specific legislative and other measures taken or envisaged to protect public health from counterfeiting of medical products and similar crimes in the context of pandemics.
8. Responses to this thematic questionnaire will be understood against the background information submitted by Parties in reply to the CPQ. Whenever warranted, Parties are invited to refer to such information. Where questions overlap between the CPQ and this questionnaire, the replies to the latter will be assessed by the Committee in order to prepare its implementation reports of the Convention with respect to the monitoring theme.
9. For the purpose of this questionnaire, the notion of pandemic will include the COVID-19 pandemic as well as other major health crises declared by the World Health Organisation as pandemics, epidemics or public health emergencies of international concern (PHEIC), including the Zika virus epidemic in 2015, the Ebola pandemic in 2014, the Middle East Respiratory Syndrome (MERS) in 2012, the H1N1 Influenza

pandemic in 2009, the H5N1 outbreak in 2005, and the severe acute respiratory syndrome (SARS) in 2003.

10. If there are differences with the information provided in the responses to the CPQ, Parties are kindly requested to specify which State bodies/agencies and, where relevant, NGOs, contributed to responding to this questionnaire.

11. As with the CPQ, Parties are kindly requested to:

- a. answer the questions regarding central, regional and local levels, to the extent possible. Federal states may, in respect of their sovereign entities, answer the questions in a summarised way;
- b. provide the relevant text (or a summary thereof), in English or French only, whenever questions/answers refer to legislation or other regulations;
- c. respond to all questions marked **mandatory** as they are essential to the monitoring round. It would be appreciated, where possible, if all questions marked **optional** could also be answered.

Prevention and Training

This section aims to collect information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics. The questions concern all those whose responsibilities it is to procure and supply medical products, and those who encounter them or their impact on public health. This section concerns awareness-raising programmes aimed at these people in particular, as well as the public in general. It concerns prevention measures aimed at raising awareness of the availability of counterfeit medical products.

Question 1. (mandatory)

Which legislative, policy, strategic and other measures have been taken to provide training with a view to preventing counterfeit medical products, active substances, excipients, accessories, parts and materials to:

- a. those involved in both public and private procurement programmes, wholesalers, and distributors of medical products to ensure that they are competent to prevent and detect counterfeit medical products and conducts that contribute to the commission of similar crimes involving threats to public health, having regard to the impact of a pandemic (Article 18.1, 2 and 3. a and c)?
- b. healthcare practitioners, police, customs, and health product regulators?
- c. specialised investigation units/bodies in the investigation of counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?

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 authorities 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.

Roszdraznadzor regularly holds both closed conference calls and seminars for representatives of its territorial bodies on topical issues of exercising powers during the pandemic, as well as interagency meetings with representatives of interested federal regulatory authorities, and also participates in seminars for healthcare professionals.

Subordinate institutions of Roszdraznadzor and the Ministry of Health of the Russian Federation (FSBI "NIC" of Roszdraznadzor, FSBI "NCESMP" of the Ministry of Health of the Russian Federation) organize educational seminars, professional development programs for healthcare professionals. During the pandemic, the training events switched to an online format, and focused on issues related to working in a pandemic, ensuring patient safety, quality control and ensuring the safety of personal protective equipment.

The issues of countering falsification are included annually in the program of annual conferences, which have been held in a remote format since 2020: "State regulation in the sphere of circulation of medicines and medical devices - "PharmMedObrascheniye", "Healthcare and quality", "Modern approaches to the expertise and registration of medicines - REGLEK".

In the conditions of large number of patients with COVID-19 in repurposed medical organizations there was a need for information support to doctors of various specialties. In April 2020, an Information Center on pharmacotherapy in patients with the new coronavirus infection COVID-19 "PharmaCOVID" was created for healthcare professionals on the basis of the Federal State Budgetary Educational Institution of Further Professional Education "Russian Medical Academy of Continuous Professional Education" of the Ministry of Healthcare of the Russian Federation (FGBOU DPO RMAPO).

The Academy of Management of the Ministry of the Interior of the Russian Federation and its branch "Bolshevo", the St. Petersburg University of the Ministry of the Interior of the Russian Federation, the Ryazan branch of the Moscow University of the Ministry of the Interior of the Russian Federation named after V.Ya. Kikotya perform annually additional professional development programs for qualification improvement of managers and members of procurement commissions to meet the needs of the Ministry of the Interior of the Russian Federation.

Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to combat illegal turnover of industrial products in the Russian Federation for the period up to 2025. The Strategy notes as one of the measures the development of human resources potential and knowledge of employees of federal executive authorities, executive authorities of the subjects of the Russian Federation, local self-government authorities in terms of countering illegal trafficking in industrial products.

Question 2. (optional)

Are there any oversight programmes to assess the frequency and effectiveness of the training provided? If so, are there revision programmes to ensure remedial actions of any deficiencies (Article 18.1, 2 and 3. a)?

Most of the advanced training programs for healthcare specialists are carried out under public-private partnership programs, at the same time the HR departments evaluate the specialist's knowledge at the end of the training program, thus monitoring the effectiveness of the training provided.

Question 3. (mandatory)

Are there awareness-raising and training programmes for all of those mentioned in question 1.a and b above and for persons and entities responsible for cleaning and waste disposal on the disposal of medical product waste at all stages of the process to prevent the recycling of medical products for the further manufacture of counterfeit medical products and instrumentalities used in the counterfeiting of medical products?

The Ministry of Health of the Russian Federation regularly updates recommendations for doctors on the prevention, diagnosis and treatment of COVID-19, sending updated information to all medical institutions. These recommendations describe the issues of turnover and disposal of medical waste, personal protective equipment: https://minzdrav.gov.ru/ministry/med_covid19

On the portal of continuing medical and pharmaceutical education of the Ministry of Health of Russia there are training materials for health professionals on the new coronavirus infection, including the explanation of the aforementioned methodological recommendations <https://edu.rosminzdrav.ru/specialistam/covid-19/>

The regulatory framework for the destruction of falsified medical products has been improved during the pandemic.

The Order of the Government of the Russian Federation as of September 15, 2020 No. 1447 approved the Rules for the destruction of the seized falsified, substandard and counterfeit medicines.

Aspects of improving the mechanism of legal regulation of the sphere of medical waste management are discussed at meetings of the Federation Council Committee on agrarian food policy and environmental management.

The Decree of the Government of the Russian Federation "On approval of the Procedure for Withdrawal from Circulation and Destruction of Falsified Medical Devices, Substandard Medical Devices and Counterfeit Medical Devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval.

Knowledge by employees of medical and pharmaceutical organizations of the relevant documents and the described rules is a licensing requirement and is included in the training and professional development programs of personnel.

Question 4. (optional)

Please outline any reviews on the effectiveness of the governance and supervision of medical product waste disposal. Are there any awareness-raising programmes on the importance of proper disposal and the risks that can arise from inadequate governance and supervision?

The methodological recommendations of the Ministry of Health of the Russian Federation for doctors on the prevention, diagnosis and treatment of COVID-19 are regularly updated.

Rosdravnadzor's information letters on the recall of falsified medical products indicate the need to withdraw and destroy these products. Such letters are published on the official website of Rosdravnadzor, promptly sent to health management authorities, wholesale and retail trade organizations, and medical organizations. Thus, the maximum speed of informing all participants in the circulation of medical products is ensured and openness to consumers is formed.

Medical and pharmaceutical organization's employees knowledge of the relevant documents and the described rules is a licensing requirement and is included in the training and professional development programs of personnel.

In accordance with part 19 of Article 38 of Federal Law No. 323-FZ, falsified medical devices and substandard medical devices are subject to withdrawal from circulation and destruction on the basis of a decision of the owner of medical devices, a decision of the authorized federal executive authority exercising functions of control and supervision in the field of health protection, or a court decision.

The rules for the destruction of withdrawn falsified medical devices, substandard medical devices and counterfeit medical devices were approved by Decree of the Government of the Russian Federation No. 1440 of September 15, 2020.

In accordance with part 6 of Article 47 of Federal Law No. 61-FZ, falsified medicines, substandard medicines are subject to withdraw and subsequent destruction or export from the Russian Federation, counterfeit medicines are subject to seizure and subsequent destruction.

In accordance with part 1 of Article 59 of Federal Law No. 61-FZ, substandard medicines, falsified medicines are subject to withdrawal from circulation and destruction in accordance with the procedure established by the Government of the Russian Federation. The basis for the destruction of medicines is a decision of the owner of medicines, a decision of the relevant authorized federal executive authority or a court decision.

The rules for the destruction of seized falsified medicines, substandard medicines and counterfeit medicines were approved by Decree of the Government of the Russian Federation No. 1447 of September 15, 2020.

The decree of the Government of the Russian Federation "On approval of the procedure for the withdrawal from circulation and destruction of counterfeit medical devices, substandard medical devices and counterfeit medical devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval.

In order to intensify prosecutorial supervision over the implementation of laws in this area, the prosecutors of the Russian Federation regions were sent a corresponding information letter in September 2021.

Question 5. (optional)

Apart from the above-mentioned general measures, please briefly describe the details of specific preventive actions targeted at specific medical products involved in any recent pandemic as well as the results achieved.

In 2020 - 2021 Interpol channels have been used to share through the territorial divisions of the National Central Bureau of Interpol of the Ministry of the Interior of Russia the alerts to the World Health Organization competent alert authorities about cases of sale of falsified medicines for preventing, detecting or treating COVID-19 and notices of the Interpol General Secretariat with "orange corner" and "purple corner" regarding fake COVID-19 tests as well as counterfeit medicines detected on the territory of the Interpol member states. .

Roszdrazhnadzor publishes information letters on its official website about falsified medicines and medical devices that have been withdrawn from circulation and are subject to destruction. (For more details, see question 23).

Since July 1, 2020, mandatory system for monitoring the movement of medicines (Track and Trace) has been introduced in the Russian Federation - labelling of medicines with datamatrix identification codes. Thus, the theft of a medicine is extremely difficult. (For more information, see question 25).

Education

This section aims at identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products.

Question 6. (mandatory)

Please elaborate on the strategies, policies and other measures that have been planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, in particular those that may be encountered during a pandemic (Article 18.3.b):

- a. on purchasing conducts of medical products, including through real world/physical and virtual means, such as online and e-commerce platforms and social media;
- b. on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems;
- c. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.

Are there any reports on the results of these measures? If so, please attach them to your responses to this questionnaire.

Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025.

The Strategy also notes that uncontrolled cross-border turnover of industrial goods, based on the use of ways and methods of "open" international Internet trade, facilitates the penetration of counterfeit and falsified products into the markets of various countries.

Among other things, the Strategy is aimed at increasing the level of intolerance of the population to the consumption of industrial products in illegal circulation by increasing consumer literacy of the population in the field of countering the circulation of counterfeit and falsified products.

In order to prevent substandard and falsified medical products from reaching patients, Roszdravnadzor promptly analyzes information from WHO, Intropol, Europol on the revealed facts of distribution of falsified, substandard or unauthorized medicines, medical devices, including products for in vitro diagnostics. In accordance with the WHO recommendations, press releases and warnings related to products for the diagnosis, prevention or treatment of coronavirus infection are posted on the official website of Roszdravnadzor. Press releases of regulatory authorities are quoted and distributed by the media.

During the pandemic, the online sale of medicines was allowed in the Russian Federation. 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:

- offer for retail sale of falsified, substandard, counterfeit medicines for human use;
- offer for the retail trade of unauthorized medicines;
- offer for remote retail sale of prescription drugs;

offer for remote retail sale of narcotic and psychotropic medicines;
etc.

In accordance with the order of the President of the Russian Federation, the management of the Ministry of Health of Russia and Roszdravnadzor regularly visits the regions, visits medical organizations, communicates with staff and patients, gives interviews, covering the situation with the prevention of the purchase of counterfeit medical products or documents on vaccination.

The issues of countering falsification are included annually in the program of annual conferences organized by Roszdravnadzor, which have been held in an online format since 2020: "State regulation in the field of circulation of medicines and medical devices - "PharmMedObrascheniye", "Medicine and quality", "Modern approaches to the expertise and registration of medicines - REGLEK". In addition, materials on countering the falsification of products are published on the official authorities websites and social networks.

Since July 2021, the Division for Interaction with Civil Society Institutions and Mass Media of the Ministry of Interior of Russia in cooperation with the territorial bodies of the Ministry of Interior of Russia has been presenting in the media and in Internet the measures taken by the internal affairs authorities to counter distribution, manufacture and sale of counterfeit COVID-19 vaccination certificates, PCR-test results, medical certificates granting the right to exemption from vaccination, as well as medical certificates indicating the presence of a high amount of antibodies and other medical documents. A total of 1170 materials were published in the media and Internet, including: federal - 624, regional - 546. The official website of the Ministry of Interior of Russia posted 58 materials prepared by territorial bodies of the Ministry of Interior of Russia, including: about stopping illegal activities for sale of documents related to vaccination against COVID-19, about detection of the Internet source where medical documents on successful vaccination were offered .

Special attention is paid to showing examples of crime investigations related to the illegal sale of medicines, since 01.01.2021 more than 20 press releases on this topic have been published on the website of the Ministry of Interior of Russia. In particular, on 12.08.2021 a material was published about the employees of the Main Medicine Control Department of the Ministry of Interior of Russia and the Main Directorate of the Ministry of Interior of Russia in the Volgograd region suppressing a large sales channel of superpotent substances.

Also, the information on the results of the work of the internal affairs authorities in this area was posted in the departmental media: in the newspaper "Shield and Sword", on the Internet portal "Ministry of Interior MEDIA", in the news releases of the radio station "Police Wave". In addition, materials on the suppression of illegal activities were published in the authority's official accounts in Instagram and Twitter.

In order to form an effective mechanism of public control, free access of industry and patients to the information resources of Roszdravnadzor in the field of countering falsification has been provided (for more details, see question 23).

Question 7. (optional)

Do public authorities have a policy to encourage or support the involvement of civil society (such as industries, publishers, academia, etc.) in the promotion of measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context? If so, please provide details.

Since 2006, the Council of Public Organizations for the Protection of Patients' Rights under the Federal Service for Surveillance in Healthcare has been functioning in which public patient organizations, the medical and academic community, public foundations and organizations of sociological research are represented. Also the composition of the Council of Public Organizations for the Protection of Patients' Rights under the Ministry of Health of the Russian Federation was approved in accordance with the Order of the Ministry of Health of the Russian Federation No. 437 dated October 23, 2012 "On the Council of Public Organizations for the Protection of Patients' Rights under the Ministry of Health of the Russian Federation".

During the parliamentary hearings, discussions are held on particularly significant issues of public importance, draft laws, international treaties subject to ratification and other issues, including in the field of falsification of medical products, with the involvement of officials, experts and the public. The hearings on health issues are initiated by the State Duma Committee on Health Protection. The hearings are broadcasted live at: <http://duma.gov.ru/multimedia/video/stream/>.

Patient organizations and associations, including associations of patients with certain or rare diseases, regularly participate in the discussion of initiatives and results of the work of the Ministry of Health of Russia and Roszdravnadzor. Information about cases of falsification of medical products, especially highly specialized products, can be promptly obtained from representatives of the patient community.

Representatives of regulatory authorities take part in professional congresses, covering, among other things, the issues of countering the falsification of medical products.

The main patient organizations of Russia: the All-Russian Union of Patients, the All-Russian Public Organizations of disabled people with Multiple Sclerosis, the All-Russian Society of Hemophilia, the Interregional Public Organization "Help for patients with cystic fibrosis", the Russian Diabetic Association, the All-Russian Society of Disabled People, the Interregional public Organization "Assistance to disabled people with Gaucher disease since childhood and their families".

For active participation in the promotion of measures to combat, prevent, detect and respond to falsified medical products, including during the pandemic, it is possible to award members of the public with a commendation, certificate of honor or other authority award.

Question 8. (optional)

Is civil society actively engaged in raising public awareness of the risks arising from counterfeit medical products (Article 18. 3, b)? If so, please provide details.

After the introduction of the mandatory traceability system for the transfer of medicines (Track&Trace), the functionality for medicines was added to the "Chestny ZNAK" mobile application. "Chestny ZNAK" is a national system of digital labeling and traceability of goods, which allows to check the legality of goods, including medical products, on the market: <https://chestnyznak.ru/en/potrebitelyam/>.

Thus, the patient can independently check with the help of a smartphone the possibility of location of a concrete medicine package in circulation.

Civil society is also involved through representatives in public councils under the Ministry of Health of Russia, Roszdravnadzor, patient organizations (see question 7).

During the parliamentary hearings, discussions are held on particularly significant issues of public importance, draft laws, international treaties subject to ratification and other issues, including in the field of falsification of medical products, with the involvement of officials, experts and the public. The hearings on health issues are initiated by the State Duma Committee on Health Protection. The hearings are broadcasted live at: <http://duma.gov.ru/multimedia/video/stream/>.

Question 9. (mandatory)

Which legislative provisions, strategies, plans and preventive measures have been taken to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8. a, and 18. 3. b)?

Advertising of medicines, medical devices and medical services is regulated by Article 24 of Federal Law No. 38-FZ of 13.03.2006 "On Advertising". Advertising of falsified and unauthorized products is prohibited by law.

In order to increase the availability of medicines, online medicines trade with a special permit was allowed in 2020. At the same time Roszdravnadzor's control over the sale of medicines via the Internet has been strengthened. Order of Roszdravnadzor N 5527 of 29.06.2020 approved criteria for blocking sites with prohibited information and putting them in the Register of prohibited sites. This measure is aimed at reducing the risk of counterfeit medical products reaching the patient. Among the criteria are:

- offer for retail sale of falsified, substandard, counterfeit medicines for human use;
- offer for the retail sale of unauthorized medicines;
- offer for online retail sale of prescription medicines;
- offer for online retail sale of narcotic and psychotropic medicines;
- etc.

By December 2021, by the decision of Roszdravnadzor, the Federal Service for Supervision of Communications, Information Technology, and Mass Media (Roskomnadzor) blocked more than 10 thousand sites.

The Ministry of Interior of Russia organized cooperation with the prosecutor's office and territorial divisions of Roskomnadzor in restricting access to information which violates the law, in accordance with the Article 15.3 of the Federal Law of July 27, 2006 № 149-FZ "On Information, Information Technologies and on the protection of information".

In April 2020, Part 1.1 of Article 238.1 of the Criminal Code of the Russian Federation was introduced, according to which the manufacture, sale or import into the territory of the Russian Federation of counterfeit medicines or medical devices committed using mass media or information and telecommunications networks, including the Internet, are considered an aggravating circumstance.

Victims

This section aims at identifying measures focused on the protection of victims' rights.

Question 10. (mandatory)

Is there any national law and policy for the protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic due to the increased risks arising? If yes, please specify it. If not, what steps are being planned, if any, for the setting of such policy or in the absence of which, for victims of crime relating to counterfeit medical products generally (Article 19)?

In accordance with Article 52 of the Constitution of the Russian Federation, the rights of victims of crimes are protected by the law, the state provides victims with access to justice and compensation for damage caused.

In accordance with part one of Article 1 of the Criminal Procedure Code of the Russian Federation (CPC), the procedure for criminal proceedings on the territory of the Russian Federation is established by the CPC, based on the Constitution of the Russian Federation. The activities of authorities and official persons carrying out criminal prosecution are aimed at achieving of criminal proceedings, which, in accordance with paragraph 1 of part one of Article 6 of the CPC, includes, the protection of the rights and legitimate interests of persons and organizations who have been victims of crimes. This principle of criminal proceedings is valid at all stages.

In addition, in the Russian Federation the system of state protection measures of the participants of criminal proceedings is established by Federal Law № 119-FZ of August 20, 2004 " State Protection of Victims, Witnesses and Other Participants of Criminal Proceedings" which determines the grounds and procedure for security measures, as well as measures of social support for these persons participating in criminal proceedings. The decision on exercising state protection is made by the court (judge), the head of the inquiry body, the head of the investigative authority or the investigator with the consent of the head of the investigative authority, who process the statement (message) about a crime or a criminal case, unless otherwise is provided by the criminal procedural legislation of the Russian Federation. The grounds for security measures are the presence of a real threat to the safety of the protected person, destruction or damage to his property in connection with his participation in criminal proceedings, which are applied by the authority that makes the decision on the exercising of state protection. Victims of crimes related to falsification of medical products and similar crimes, including periods of pandemics, if there are reasons established by the Federal Law № 119-FZ of August 20, 2004, are subject to state protection on an equal basis with victims of other types of crimes.

According to paragraph 3 of Article 42 of the Code of Criminal Procedure, 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.

In accordance with the Federal Law "On the procedure for reviewing appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, citizens, as well as legal entities, can apply to a state body, and their appeal is necessarily subject to consideration.

Agreements and algorithms for interaction and exchange of information in the field of countering the circulation of falsified and counterfeit medicines and medical devices concluded by Roszdravnadzor with the Ministry of Interior of Russia, the Federal Customs Service of Russia, the Investigative Committee of the Russian Federation provide that information received from citizens can serve as a basis for the start of control-supervisory and investigative measures.

Question 11. (optional)

Are measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4)?

In accordance with part three of Article 11 of the CPC, if there is sufficient evidence that the victim, witness or other participants in criminal proceedings, as well as their relatives and partners are threatened with murder, violence, destruction or damage to their property or other dangerous unlawful acts, the court, the prosecutor, the head of the investigative authority, the investigator, the inquiry body, the head of the inquiry department, the head of the inquiry unit and the interrogator take within their competence in relation to these persons the security measures provided in part nine of Article 166, part two of Article 186, part eight Articles 193, paragraph 4 of the second part of Article 241 and the fifth part of Article 278 of the Criminal Procedure Code, as well as security measures provided by the legislation of the Russian Federation. Among the legislative acts regulating the application of security measures is the Federal Law No. 119-FZ of August 20, 2004, according to which security measures can be applied at all stages of criminal proceedings.

Question 12. (optional)

What measures are provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceeding and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health? Please provide information on any such organisations and groups/bodies. Please provide information on any assessment of the effectiveness of such involvement by such providers (Article 20.5).

According to paragraph 8 of the second part of Article 42 of the Code of Criminal Procedure, the victim has the right to have a representative. If a legal entity is recognized as a victim, its rights are exercised by a representative (part nine of Article 42 of the CPC). The representatives of the victim, of the civil plaintiff and of the private prosecutor can be lawyers, and the representatives of the civil plaintiff, who is a legal entity, can also be other eligible persons in accordance with the CPC of the Russian Federation to represent his interests. As a representative of the victim or civil plaintiff, one of the close relatives of the victim or civil plaintiff, or another person, whose admission is requested by the victim or civil plaintiff, may be admitted (part one of Article 45 of the Code of Criminal Procedure). Representatives of the

victim, civil plaintiff and private prosecutor have the same procedural rights as the persons they represent (part three of Article 45 of the CCP). Participation in the criminal case of the representative of the victim does not deprive him of the rights provided by part ten of Article 42 of the CCP.

Patients can seek support from patient organizations and associations, for example, the All-Russian Union of Patients, the All-Russian Public Organization of Disabled People with Multiple Sclerosis, the All-Russian Society of Hemophilia, the Interregional Public Organization "Assistance to patients with Cystic Fibrosis", the Russian Diabetic Association, the All-Russian Society of Disabled People, the Interregional public Organization "Assistance to disabled people with Gaucher's disease and their families", etc. Also in Russia, the rights of victims are protected by ombudsmen, including the Plenipotentiaries under the President of the Russian Federation for human rights, for the rights of the child, for the protection of the rights of entrepreneurs, for the rights of students.

Question 13. (optional)

Is civil society actively engaged in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b)? If so, please provide details.

Question 14. (optional)

What measures are in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention? Is there any oversight to assess the effectiveness of such measures? If so, please briefly describe the results (Article 22.1).

In accordance with the second part of Article 21 of the CPC, in each case of detection of signs of a crime, the prosecutor, investigator, body of inquiry and interrogating officer take measures provided for by the CPC to establish the event of a crime, to expose the person or persons guilty of committing the crime. The reasons for initiating a criminal case are, among other things, a statement of a crime (paragraph 1 of part one of Article 140 of the CCP), as well as a message about a committed or impending crime received from other sources (paragraph 3 of part one of Article 140 of the CCP). The interrogator, the inquiry body, the investigator, the head of the investigative authority are obliged to accept, check the report of any committed or impending crime and, within the competence established by the Criminal Procedure Code, make a decision on it (part one of Article 144 of the Criminal Procedure Code). According to the information about the crime spread in the mass media, the inquiry is carried out by the inquiry authority on behalf of the prosecutor, and also by the investigator within the instructions of the head of the investigative authority (part two of Article 144 of the Criminal Procedure Code). Part four of Article 7 of the Code of Criminal Procedure directly states that the decisions of the investigator, the inquiry body, the head of the inquiry body, the head of the unit of inquiry, the interrogator must be lawful, reasonable and motivated. Compliance with this requirement is guaranteed by the provisions of the Code of Criminal Procedure, in particular those regulating issues of judicial and authority control, as well as prosecutorial supervision over the procedural activities of the authorities of inquiry and preliminary investigation authorities (Article 125, paragraph 2 of the first part of Article 39,

paragraph 1 of the second part of Article 37, paragraph 1 of the third part of Article 40.1, paragraph 3 of the first part of Article 40.2), a special procedure for extending the deadlines for checking a report about crime (part three of Article 144 of the CCP), the requirement to inform the applicant about the decision made based on the results of the verification of the report about crime (part two of Article 145, parts third and fourth articles 148 of the CPC).

In order to improve legislation in the field of protection of the rights of victims, a working group has been formed on behalf of the President of the Russian Federation to prepare proposals for amendments to the Criminal Procedure Code of the Russian Federation in terms of optimizing the stage of initiation of criminal proceedings. This work is under the control of the Commissioner for Human Rights in the Russian Federation and is carried out with the participation of the Prosecutor General's Office, scientific institutions and the Victims of Crime Support Fund (part of the European Victim Support Association – Victim Support Europe).

Citizens may appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact by phone hotline, or send a complaint through the Unified Portal of Public Services. Such appeals must be considered in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ. Compliance with the requirements of this Federal Law is monitored by the Prosecutor's Office.

Information about offenses in the presence of signs of a criminal offense is transmitted accordingly to investigative or law enforcement authorities.

Cooperation and information exchange

This section focuses on the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation.

Question 15. (mandatory)

Please provide information on measures that your country has taken or plans to take to adopt a national strategy and/or formal action plan on cooperation and information exchange between authorities/bodies to combat counterfeiting of medical products and similar crimes and whether they specifically make provision for pandemic situations (Article 17.1).

Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025.

The Strategy is designed to ensure coordinated interaction of interested state authorities, market participants and consumers at the federal, regional and local levels, including through the use of interstate mechanisms to counter the illegal import, manufacture and turnover of industrial products on the territory of the Russian Federation.

Among the priorities of the Strategy are:

increasing the level of coordination of public authorities in the implementation of control and supervisory activities,

increasing the control and interaction of the authorities of the Russian Federation with the authorities of the member states of the Eurasian Economic Union in the field of movement

of counterfeit and falsified products across the customs border of the Eurasian Economic Union.

The strategy of medicines supply to the population of the Russian Federation for the period up to 2025, approved by the order of the Ministry of Health of Russia dated February 13, 2013 N 66, providing for the establishing a system of effective cooperation of interested federal executive authorities, executive authorities of the constituent entities of the Russian Federation and public organizations will achieve coordinated actions in the implementation of the Strategy's activities.

One of the prospects for the implementation of the Strategy is: "Through the implementation of measures included in the Strategy for the development of the state system for ensuring and controlling the quality, efficacy and safety of medicines for human use it is planned to significantly reduce the existing risks associated with the circulation of falsified and substandard products, as well as with adverse events of medicines for human use".

Question 16. (optional)

- a. Is the implementation of such national strategy and/or action plan supported and underpinned by enabling legislation for the transfer and receipt of information and data between authorities/bodies and to and from other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2)?
- b. Are there specific Memorandum of Understanding (MOU) and/or Data Sharing Agreements (DSA) between bodies, at national and international levels, to give effect to arrangements between authorities/bodies in combating counterfeit medical products and similar crimes. Have they been adopted specifically because of the COVID-19 pandemic?
- c. Please describe briefly, and without going into detail, the practical measures that ensure the implementation and effectiveness of the MOUs and DSAs, including periodic reviews.

The interaction of the Ministry of Interior of Russia with Roszdravnadzor is carried out within the framework of the Agreement dated July 31, 2015 № C2 / 15/1/6054 "On the procedure for interaction in terms of counteracting the circulation of falsified, counterfeit, substandard and unauthorized medicines and medical devices."

The Ministry of Interior of Russia collectively with the Federal Security Service of Russian, Federal Customs Service of Russia and Roszdravnadzor annually conduct the international police operation "Pangea", aimed at combating crimes in the field of illegal circulation of medicines and medical devices. The coordinator of the event on the territory of the Russian Federation is the National Central Bureau of Interpol of the Ministry of Interior of Russia.

Interdepartmental electronic interaction has been organized between the Federal Customs Service of Russia and the Ministry of Health of Russia, within the framework of which the customs authorities, when performing customs operations, receive information about the permits contained in the information resources of the Ministry of Health of the Russian Federation in automatic mode, close to real time.

The Federal Customs Service of Russia, within the framework of the "Agreement on Interaction between the Federal Service for Surveillance in Healthcare and the Federal

Customs Service, when providing and receiving information” dated September 10, 2013, sends to Roszdravnadzor, at its request, data on cases of administrative offenses relating to the circulation of goods, the surveillance of which relates to the established sphere of Roszdravnadzor.

These agreements describe the procedure for exchanging information between authorities, the timing of its transmission, the timing of expertise (if necessary) and the provision of expert opinions.

Roszdravnadzor sends information about the decisions taken on the introduction of Internet resources offering counterfeit products for sale to Roskomnadzor in accordance with Roszdravnadzor’s Order No. 5527 of 29/06/2020 (see question 6) and the Decree of the Government of the Russian Federation No. 1101 of 26/10/2012 describing the operation of the Unified Register of Domain Names, indexes of pages of sites containing information which distribution is prohibited in the Russian Federation.

Also, within the framework of memorandums of understanding signed between Roszdravnadzor and regulators of foreign states that have not ratified the Medicrime Convention, for example Kazakhstan, Serbia, China, India, Cuba, Brazil, Argentina, Iran, etc., information exchange is carried out on the quality, efficacy and safety of medicines and medical devices, including information on the detection of falsified products.

Question 17. (optional)

Please state on cooperation arrangements which authority has the lead and which participate in the operation of the plans and what oversight exists on the operation of the plans. Please describe briefly, without going into detail, the main areas of responsibility of the participating authorities.

Roszdravnadzor is the federal executive authority that performs the function of control and supervision in the field of healthcare. In addition to the above, Roszdravnadzor forms a list of foreign medicines to which the risk profile is applied by the customs authorities when importing medicines into the territory of the Russian Federation.

Roszdravnadzor, having a laboratory base for quality control of medicines and medical devices, analyzes samples of allegedly falsified or counterfeit products received from the Ministry of Interior of Russia.

Question 18. (optional)

Do any arrangements involve cooperation arrangements with civil society, with industry or service providers (such as financial and money transfer services, e-commerce, social media platforms providers, logistics – including postal and delivery services, etc.)? If so, please briefly describe these arrangements and whether they took place during or because of a pandemic.

In addition to the previously mentioned patient organizations, Roszdravnadzor actively interacts with specialized associations from the industry: the Association of Russian Pharmaceutical Manufacturers (ARPM), the Association of International Pharmaceutical Manufacturers (AIPM), the National Association of Manufacturers of Pharmaceutical Products

and Medical Devices "APF", the Russian Association of Pharmacy Networks (RAPN), the Association of Pharmaceutical Manufacturers of the EAEU.

Question 19. (optional)

Please provide details on the membership or arrangements with bodies/groups dedicated to combating counterfeit medical products and similar crimes, whether investigative or advisory in nature. In your reply, please differentiate bodies/groups that put an emphasis on counterfeit medical products but are not solely dedicated to combating counterfeit medical products and similar crimes involving threats to public health.

Question 20. (optional)

Does the national strategy/action plan on counterfeit medical products stipulate or facilitate the establishment of a point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities? Is there any oversight of the effectiveness of this process? Please provide information on the effectiveness of this process.

Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025.

Among the principles of the formation and implementation of measures in the field of combating illegal trafficking of industrial products in the Russian Federation are:

coordination of efforts of federal executive authorities, executive authorities of constituent entities of the Russian Federation, local self-government bodies, bona fide manufacturers and sellers, citizens (consumers), organizations representing their interests to combat illegal trafficking of industrial products;

improvement of the current mechanism of interaction of state authorities on combating illegal trafficking of industrial products;

introduction of control indicators of the effectiveness of the authorities activities in identifying, preventing violations in the sphere of turnover of industrial products and in conducting penalties for such violations.

Interdepartmental coordination in the implementation of measures to counteract the illegal turnover of industrial products, as well as control over the progress of their implementation, is carried out by the State Commission and the commissions of the subjects of the Russian Federation.

The progress of the implementation of measures and activities, the results of monitoring of their implementation are reflected in the annual report of the State Commission on the situation in the sphere of illegal turnover of industrial products on the territory of the Russian Federation, which is submitted to the Government of the Russian Federation.

In accordance with the Decree of the Government of the Russian Federation dated 05.03.2021 N 551-r, the "Concept of a system for monitoring and assessing the situation in the field of countering illicit turnover in industrial products in the Russian Federation" was approved in order to improve the quality and efficiency of decision-making on prevention, detection, suppression, minimization of consequences of illicit turnover of industrial products in the Russian Federation.

Question 21. (optional)

Is there a point of contact specified for the international exchange of information relating to the counterfeiting of medical product, such as product alerts and analytical reports from laboratory investigations, that has different arrangements from other points of contact? Please provide any rationale for this difference.

Representatives of Roszdravnadzor and the Ministry of Health of Russia take part in the work of international initiatives to identify and prevent the spread of falsified medical products, such as CMED, WGEO, APEC, WHO Member State Mechanism to address the issue of SF medical products, United Nations Office on Drugs and Crime (UNODC). In accordance with clause 5.15. of the Decree of the Government of the Russian Federation of 30.06.2004 N 323 "On approval of the Regulations of the Federal Service for Surveillance in the Field of Healthcare" Roszdravnadzor interacts in accordance with the established procedure with state authorities of foreign states and international organizations in the established field of activity, and is the only contact point in Russia for cooperation with foreign regulators and organizations on issues of falsification of medical products.

As a part of PIC/S membership application process (submitted in December 2020) Roszdravnadzor as a contact point is connected to the system of Handling Rapid Alerts and Recalls Arising from Quality Defects.

Roszdravnadzor has also concluded bilateral memorandums of understanding with a number of foreign countries. The documents provide for information exchange on the facts of detection of substandard, falsified, counterfeit products in circulation.

Question 22. (mandatory)

Is the exchange of information or transfer and receipt of data and evidence between bodies/countries supported and underpinned by enabling legislation?

In accordance with the Strategy on Combating Illicit Trafficking in Industrial Products in the Russian Federation for the period up to 2025, the international cooperation of the Russian Federation in the field of combating illicit trafficking in industrial products provides for cooperation with international organizations whose activities are aimed, inter alia, at countering illicit trafficking in industrial products, including the exchange of experience with foreign countries.

In accordance with paragraph 4 of the second part of Article 38 and paragraph 1.1 of the third part of Article 41 of the Criminal Procedure Code, the investigator (interrogator) is authorized to give the authority of inquiry in the cases and in the procedure established by the Criminal Procedure Code binding written instructions on the performance of certain investigative actions, other procedural actions, as well as receive assistance in their implementation.

For example, according to part one of Article 152 of the Criminal Procedure Code, if it is necessary to carry out investigative or search actions in another place, the investigator has the right to carry out them personally or to entrust the performance of these actions to the investigator or the authority of inquiry. The interrogator has the right to carry out them

personally or to entrust the performance of these actions to the inquiry officer or authority of inquiry. Orders must be executed no later than 10 days. Part five of the Criminal Procedure Code establishes the procedure for international cooperation in the field of criminal proceedings.

In particular, in accordance with the first part of Article 453 of the CPC, if it is necessary to conduct an interrogation, examination, seizure, search, forensic examination or other procedural actions provided for by the CPC in a foreign state, the court, the prosecutor, the investigator, the head of the investigative authority, the interrogator makes a request for their performance by a competent authority or an official of a foreign state in accordance with an international treaty of the Russian Federation, an international agreement or on the basis of the principle of reciprocity. Evidence obtained on the territory of a foreign state by its officials in the course of their execution of orders for the provision of legal assistance in criminal cases or sent to the Russian Federation in an appendix to the order on the implementation of criminal prosecution in accordance with international treaties of the Russian Federation, international agreements or on the basis of the principle of reciprocity certified and transferred in accordance with the established procedure, have the same legal force as if they were received on the territory of the Russian Federation in full compliance with the requirements of Article 455 of the Criminal Procedure Code.

In order to combat smuggling, including in the field of illegal movement of falsified medical products across the customs border of the EAEU, on the basis of the FCS 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 (hereinafter - the CIS) dated 15.09.2016 № 7/64 within the framework of the activities of the Regional Communication Center for Law Enforcement of the World Customs Organization for the CIS countries, a contact point operates 24 hours on the basis of the international law enforcement communication platform of the World Customs Organization CENcomm.

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

Representatives of Roszdravnadzor and the Ministry of Health of Russia take part in the work of international initiatives to identify and prevent the spread of falsified medical products, such as CMED, WGEO, APEC, WHO Member State Mechanism to address the issue of SF medical products, United Nations Office on Drugs and Crime (UNODC).

As part of the application for membership of the Russian Federation in PIC/S (submitted in December 2020) Roszdravnadzor as a contact point is connected to the Handling Rapid Alerts and Recalls Arising from Quality Defects System.

Detection

This section seeks to understand and appreciate the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and to prevent them from reaching patients.

Question 23. (mandatory)

Are there legislative or other measures to ensure that industry can promptly report suspicions or detections of counterfeit medical products and similar crimes involving threats to public health, to any particular authority? Are there established or ad hoc procedures and processes for this reporting?

In accordance with the Federal Law "On the procedure for reviewing appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, the appeal of citizens and legal entities to the state body is necessarily subject to consideration.

Such an appeal may serve as a basis for conducting control and supervisory measures. Article 57 of the Federal Law of 12.04.2010 No. 61-FZ "On the Circulation of Medicines" prohibits the sale of falsified, substandard and counterfeit medicines.

Art. 4, paragraph 26.1 of the Federal Law of 12.04.2010 No. 61-FZ established that the MAH (marketing Authorisation Holder) of the medicine is responsible for the quality, efficacy and safety of the medicine.

Upon receipt of information about a possible substandard quality of a medicine batch, the holder informs Roszdravnadzor about the decision to withdraw the batch of a medicine, which is published on the Roszdravnadzor website in the form of an information letter for subjects of medicines circulation. The actions of Roszdravnadzor are reflected in the relevant SOPs.

On the official website of Roszdravnadzor in the section "Search for withdrawn medicines" information is provided on medicines that have been withdrawn from circulation due to their substandard quality: <https://roszdravnadzor.gov.ru/services/lssearch>.

By Art. 38 of the Federal Law of 21.11.2011 N 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation" (as amended and supplemented, entered into force on 01.10.2021) it is prohibited to import into the territory of the Russian Federation as well as to sell falsified, substandard and counterfeit medical devices.

Roszdravnadzor information letters on monitoring the safety of medical devices are posted in the electronic service "Information letters about medical devices": <https://roszdravnadzor.gov.ru/services/unreg>

In the territorial bodies of the Ministry of Interior of Russia reception, registration and permission of statements and reports about crimes is carried out in accordance with the Instruction on the procedure for receiving, registration and permission in the territorial bodies of the Ministry of Interior of the Russian Federation of statements and reports of crimes, administrative offenses, incidents, approved by the order of the Ministry of Interior of Russia dated August 29, 2014 No. 736 (hereinafter referred to as the Instruction). In accordance with clause 8 of the Instruction statements and reports of crimes, regardless of the place and time of the crime, as well as the completeness of the information contained in them and the form

of submission, are subject to compulsory reception in all territorial bodies of the Ministry of Interior of Russia.

Registration in the Book of records of statements and messages about crimes, administrative offenses, incidents (hereinafter - BRMC) of statements and messages about crimes is carried out regardless of the operational service area immediately and 24 hours in the duty units of the territorial bodies of i of the Ministry of Interior of Russia (paragraph 23 of the Instruction). Electronic statements are printed on paper, further work is carried out with them as with written statements about crimes, administrative offenses, incidents in the manner prescribed by paragraph 11 of the Instruction. Statements of crimes contained in written applications sent through postal operators with the delivery of written correspondence to the building of the territorial body of the Ministry of Interior of Russia, official sites, facsimile communications, federal courier communications and special communications, mailbox, received during a personal reception are accepted by the division of office work and regime of the territorial body of the Ministry of Interior of Russia, are registered in the prescribed order and are sent by the head (chief) of the territorial body of the Ministry of Interior of Russia to the duty unit of the territorial body of the Ministry of Interior of Russia for immediate registration with the BRMC (clause 12 of the Instruction).

Section V of the Instruction establishes the procedure for monitoring compliance with the procedure for receiving, registering and resolving statements and reports of crimes. In particular, paragraph 72 of the Instruction stipulates that the head (chief) of the territorial body of the Ministry of Interior of Russia bears personal responsibility for compliance with the law when accepting, registering and resolving statements and reports of crimes; ensures daily control over the deadlines for resolving statements and reports of crimes, as well as the correctness of maintaining the BRMC with a record of this in the book of reception and delivery of duty.

Question 24. (mandatory)

Is there a market sampling programme established to detect counterfeit medical products on the market? If so, which authority is responsible for this? Is this system sustainable in times of pandemic having regard to the additional demands placed on analytical laboratories and testing services by the impact of the pandemic? Are there oversight arrangements to ascertain the effectiveness of these measures?

Article 9 of the Federal Law of April 12, 2010 № 61-FZ "On the Circulation of Medicines" provides for the following control and supervisory measures in the implementation of federal state control in the field of circulation of medicines:

- 1) documentary verification;
- 2) on-site inspection;
- 3) selective quality control;
- 4) test purchase;
- 5) inspection visit;
- 6) monitoring compliance with mandatory requirements (safety monitoring) (pharmacovigilance).

Article 95 of the Federal Law of 21.11.2011 No. 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation" provides for the following control and

supervisory measures in the implementation of federal state control (surveillance) over the circulation of medical devices:

- 1) documentary verification;
- 2) on-site inspection;
- 3) selective control;
- 4) test purchase;
- 5) inspection visit;
- 6) monitoring compliance with mandatory requirements (safety monitoring).

Control and surveillance activities are carried out in accordance with the requirements of the Federal Law of July 31, 2020 No. 248-FZ "On State Control (Surveillance) and Municipal Control in the Russian Federation". In accordance with Article 65 of Federal Law No. 248-FZ, as part of control (supervisory) actions, sampling (samples) may be carried out, among other measures.

Federal state control (surveillance) in the field of circulation of medicines is carried out in accordance with the Decree of the Government of the Russian Federation dated June 29, 2021 No. 1049.

Federal state control (surveillance) over the circulation of medical devices is carried out in accordance with the Decree of the Government of the Russian Federation dated June 30, 2021 No. 1066.

In accordance with the Regulation on the Federal Service for Surveillance in Healthcare, approved by Decree of the Government of the Russian Federation No. 323 dated June 30, 2004, state control over the circulation of medical devices and medicines is attributed to the powers of Roszdravnadzor.

Selective quality control of medicines for human use is conducted in accordance with the Order of Roszdravnadzor No. 5539 dated August 7, 2015.

When forming a plan for quality selective control, Roszdravnadzor, among other, takes into account:

data on the identification of substandard and falsified medicines,
information on the quality of medicines contained in appeals and statements of citizens, legal entities, individual entrepreneurs, information from state authorities, local governments, from the media.

A group of medicines for the treatment of coronavirus infection was included into the Plan of selective quality control of medicines for 2021, approved on 25.12.2020 by Roszdravnadzor Letter No. 01i-2451/20 (posted in public access on the official website of Roszdravnadzor <https://roszdravnadzor.gov.ru/drugs/qualitycontrol/documents/b579>). As a part of selective control released batches of medicines for COVID-19 treatment are selected and tested in federal laboratories.

Question 25. (mandatory)

Do these sampling programmes, mentioned in question 24 above, cover public procurement of medical products to detect counterfeit medical products being used in the public health system, such as in hospitals, and not procured for supply by sale to the trade or public? If not, are there arrangements to introduce such a programme?

Federal state control (surveillance) may be applied to any medical products in circulation on the territory of the Russian Federation including in a wholesale organization, in a retail network, in a medical institution.

The implementation of a system to monitor the movement of medicines (Track and Trace) contributed to the identification of offenses in the sphere of circulation of expensive medicines. In particular, even at the stage of the experiment on the implementation of the Track and Trace system in the Russian Federation facts were revealed when medicines were purchased under government contracts, stolen and re-sold under government contracts in other regions of the Russian Federation.

An example of such an investigation is given in the press release of the territorial body of Roszdravnadzor: <https://78reg.roszdravnadzor.gov.ru/news/23617>.

In accordance with Article 67 of Federal Law No. 61-FZ of 12.04.2010 "On Circulation of Medicines", mandatory labelling of medicines has been introduced since July 1, 2020.

At the moment, an experiment on the labelling of wheelchairs related to medical devices has been completed on the territory of the Russian Federation

The most important prospect in the circulation of medical devices, especially high-tech equipment and mass-consumption products, should be the implementation of mandatory labelling of medical devices by means of identification and the creation of an information system that allows identifying a unit of a medical device based on the information embedded in this labelling.

Relations aimed at ensuring state and municipal needs in order to increase the efficiency and effectiveness of procurement, to ensure publicity and transparency, to prevent corruption and other abuses are defined by Federal Law No. 44-FZ of 05.04.2013 "On the contract system in the procurement of goods, works, services for state and municipal needs". Article 94 provides for the possibility for the customer to conduct an examination of the delivered goods. The execution of the requirements of federal legislation is controlled by the Prosecutor General's Office.

Question 26. (mandatory)

Are there laws and policies in place to enable customs services to detect, detain and act on a counterfeit medical product, as defined in Article 4.j, different to the intellectual property counterfeiting? Do the laws and policies enable customs services to take action without reference to a rights holder notwithstanding that the same medical product may also infringe an intellectual property right?

In accordance with the Customs Code of the EAEU, the customs authorities, within their competence, ensure the fulfillment of objectives to protect human life and health, rights to intellectual property, the rights of consumers of goods imported into the Russian Federation.

The crimes against which the Medicrime Convention is directed are investigated regardless of intellectual property rights.

The customs authorities are authorized to amount protocols on the administrative offense (AO) under Article 6.33 of the Code of Administrative Offenses of the Russian Federation within their competence - for offenses related to the import into the territory of the Russian Federation of falsified medicines, medical devices, nutritional supplements,

counterfeit medicines and medical devices, if these actions do not contain a criminal offense (part 1 of article 6.33 of the Code of Administrative Offenses of the Russian Federation).

In the event that customs officials identify other AOs (production, sale, realization) under Article 6.33 of the Code of Administrative Offenses of the Russian Federation, such materials are sent to the territorial bodies of Roszdravnadzor in accordance with Cooperation Agreement.

At the same time, the Customs Code of the Eurasian Economic Union grants customs authorities powers in the field of regulating the protection of intellectual property rights, known as *ex officio*. It provides for the possibility to suspend the release of goods for 10 days if the customs authority has detected signs of violation of the rights of the copyright holder to intellectual property objects. At the request of the copyright holder this period can be extended up to 10 more days.

Investigation and Prosecution

This section concerns the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic.

Question 27. (mandatory)

Please outline through the following measures how is the criminalisation of offences achieved in order to enable effective investigation and prosecution.

- a. To what extent does the notion of 'medical products' in internal law fully corresponds to the definition in Article 4.a, even if the term is not specifically defined?
- b. To what extent does the notion of 'counterfeiting' in internal law fully corresponds with the definition by Article 4.j as regards medical products? What steps have been taken to ensure that this has been or will be achieved?
- c. Please outline what steps have been taken to ensure that offences relating to counterfeit medical products, as defined in Articles 4.a and 4.j, are criminalised in accordance with Articles 5 and 6.
- d. Please outline what steps have been taken to ensure that intentional offences described in Article 8 relating to medical products, as defined in Article 4.a, are criminalised.
- e. Please outline what steps have been taken to ensure that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products.
- f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)?

The concepts of “medical products” and “falsification” fully comply with the definitions of the Convention (see the responses to the General Overview Questionnaire).

In accordance with part 37 of article 4 of the Federal Law of April 12, 2010 № 61-FZ "On the Circulation of Medicines", a falsified medicine is a medicine accompanied by false information about its composition and / or manufacturer.

In accordance with Part 12 of Article 38 of Federal Law № 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation", a falsified medical device is a medical device accompanied by false information about its characteristics and (or) the manufacturer.

The Criminal Code of the Russian Federation (hereinafter referred to as the Criminal Code) contains norms aimed at protecting people from criminal offences related to falsification of medical products, as well as illegal circulation and forgery of documents.

In particular, Article 235.1 (Illegal production of medicines and medical devices) of the Criminal Code establishes responsibility for the production of medicines or medical devices without a special permit (license), if such a permit (such license) is mandatory (mandatory).

In accordance with article 238.1 (Circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements) of the Criminal Code the production, sale or import into the territory of the Russian Federation of falsified medicines or medical devices, or the sale or import into the territory of the Russian Federation of substandard medicines or medical devices, or illegal production, sale or import into the territory of the Russian Federation for the purpose of marketing unauthorized medicines or medical devices, or the production, sale or import into the territory of the Russian Federation of falsified nutritional supplements containing pharmaceutical substances undeclared during state authorization committed on a large scale.

Also, Article 327.2 of the Criminal Code provides for criminal liability for the manufacture for the purpose of use or sale or the use of knowingly forged documents for medicines or medical devices (authorization certificate, certificate or declaration of conformity, instructions for the use of a medicine or regulatory, technical and operational documentation of the manufacturer of a medical device).

In a pandemic, on the basis of Federal Law № 95-FZ dated 01.04.2020, Article 238.1 of the Criminal Code of the Russian Federation was supplemented with part 1, which provides for liability for “circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements using the mass media or information and telecommunication networks, including the Internet”.

These changes are due to the fact that in the context of the pandemic, online stores have gained increased demand, which can be used by fakers of medicines, offering medicines at a lower price, as well as medicines that are supposedly effective for treating or preventing a new coronavirus infection.

In addition, in relation to actions on the circulation of falsified, counterfeit, substandard and unauthorized medicines, medical devices, as well as falsified nutritional supplements that do not contain a criminal offense, administrative liability is provided under Article 6.33 of the Code of Administrative Offenses of the Russian Federation.

According to the data of the state statistical reporting, in 2020, criminal cases on 7 crimes provided for by Article 235.1 of the Criminal Code of the Russian Federation "Illegal production of medicines and medical devices" were in the proceedings of the investigating authorities. Criminal cases about 4 of them were sent to the court for consideration on the merits (in the first half of 2021 - 2 and 2, respectively).

There were also criminal cases on 185 criminal acts provided for in 238.1 of the Criminal Code of the Russian Federation "Circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements." Criminal cases about 26 of them were sent to court (in the first half of 2021 - 64 and 53, respectively).

Question 28. Framework for investigation and prosecution (mandatory)

Please provide information, specifically in relation to counterfeit medical products and similar crimes involving threats to public health, on:

- a. any national specialised investigation units dedicated to:
 - 1) conducting criminal investigations, and/or
 - 2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure;
- b. any specialised prosecutors and whether they function on a national or local basis.

If neither a or b apply, please describe briefly the framework used for specialised investigations and prosecutions to ensure that the full understanding of the crimes involved are taken into consideration.

In accordance with the provisions of Article 151 of the Code of Criminal Procedure of the Russian Federation preliminary investigation in criminal cases of crimes provided for by Articles 235.1, 238.1 and 327.2 of the Criminal Code of the Russian Federation is carried out by investigators of the Investigative Committee of the Russian Federation; crimes provided for by Article 226.1 of the Criminal Code of the Russian Federation - by investigators of the Federal Security Service, investigators of the internal affairs authorities, as well as investigators of the authority that identified these crimes.

Question 29. (mandatory)

In relation to the investigation of counterfeit medical products and similar crimes involving a threat to public health, please indicate, without entering into detail:

- a. the process in place, or planned, for deciding which investigation unit/body takes responsibility/the lead for investigations in general or as they occur;
- b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3. b).

The reasons and grounds for initiating criminal cases on crimes of this category are of a general nature and are provided in Article 140 of the Code of Criminal Procedure of the Russian Federation.

If there is a need for an expert opinion on the presence/absence of signs of falsification in a particular product, the Ministry of Interior sends a request to Roszdravnadzor to issue a corresponding order to the laboratories subordinate to Roszdravnadzor. The order of work is fixed by the Agreement and the algorithm of interaction between Roszdravnadzor and the Ministry of Interior of Russia on the suppression of the turnover of falsified, substandard and unauthorized medicines and medical devices.

Question 30. (optional)

Please provide details of any dedicated facility available for the public to report information to investigating authorities (this does not relate to pharmacovigilance or product quality defect reports). Please provide details of whether the reporting is done by telephone, email, via an online platform, or other means, and whether this is a confidential report system. Is the reporting system reviewed for effectiveness? Please provide your assessment of the effectiveness of such facility.

Citizens can leave an appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact the hotline by phone, or send a complaint through the Unified Portal of Public Services (<https://www.gosuslugi.ru/>). Such appeals in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ must be considered. Compliance with the requirements of federal legislation is monitored by the Prosecutor General's Office.

Citizens' appeals and the timely response to them are recorded and monitored in a special closed subsystem of the Automated Information System of Roszdravnadzor.

Similar forms of filing appeals are provided in all federal executive authorities (the Ministry of Health of the Russian Federation, the Ministry of Interior, the Prosecutor General's Office, etc.).

Information about offenses with the presence of criminal offense signs is transmitted to according investigative or law enforcement agencies.

Question 31. (mandatory)

Are complaints on counterfeit medical products and similar crimes collated on a national basis for record keeping, analysis, and effective investigation or dealt with on an ad hoc basis by individual investigating authorities/bodies?

Acceptance, registration and permission in the territorial bodies of the Ministry of Interior of Russia of statements and reports of crimes is carried out in accordance with the Instruction on the procedure for acceptance, registration and permission in the territorial bodies of the Ministry of Interior of the Russian Federation of statements and reports of crimes, administrative offenses, incidents, approved by the order of the Ministry of Interior of Russia dated August 29, 2014 No. 736. The detailed answer is given in question 23.

The interaction of the Ministry of Interior of Russia with Roszdravnadzor is carried out within the framework of the Agreement dated July 31, 2015 No. C2/15/1/6054 "On the procedure for cooperation in terms of countering the turnover of falsified, counterfeit, substandard and unauthorized medicines and medical devices."

In accordance with the Federal Law "On the procedure for considering appeals of Citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, citizens, as well as legal entities, can apply to a state authority, and their appeal is obligatory subject for consideration.

Citizens can submit an appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact the hotline by phone, or send a complaint through the Unified Portal of Public Services. Such appeals in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N

59-FZ must be considered. Compliance with the requirements of this Federal Law is monitored by the Prosecutor's Office.

Information about offenses in the presence of signs of a criminal offense is transmitted to investigative or law enforcement authorities.

Agreements and algorithms for cooperation and exchange of information in the field of countering the circulation of falsified and counterfeit medicines and medical devices concluded by Roszdravnadzor with the Ministry of Internal Affairs of Russia, the Federal Customs Service of Russia, the Investigative Committee of the Russian Federation provide that information received from citizens can serve as a basis for the start of control and supervisory and investigative measures.

Roszdravnadzor publishes information letters for the subjects of circulation about the facts of the identification of falsified, counterfeit, substandard medicines on its official website in the section "Search for medicines withdrawn from circulation".

This service provides information about medicines that have been withdrawn from circulation due to non-compliance with their quality. The search parameters are: the trade name of the medicine, the batch number, the name of the manufacturer, the country of manufacture, the status of the medicine, the number of the information letter or the time period: <https://roszdravnadzor.gov.ru/services/lsearch>.

Decisions of Roszdravnadzor on medical devices that do not meet the established requirements or are in circulation in violation of the legislation of the Russian Federation are posted on the official website of Roszdravnadzor in the section "Information letters about medical devices": <https://roszdravnadzor.gov.ru/services/unreg>.

In addition, accounting of all cases of falsification of medical products is carried out in the closed part of the Automated Information System of Roszdravnadzor, indicating the full name of the responsible employee of Roszdravnadzor. The official duties of Roszdravnadzor employees involved in the consideration of issues of the circulation of substandard or falsified medical products are fixed in the job descriptions developed within the framework of the Roszdravnadzor quality management system. Also, the QMS of Roszdravnadzor includes SOPs that determine the procedure for reviewing complaints on the issue of falsification, including interaction with other authorities.

Question 32. (mandatory)

Are all prescribed offences in Articles 5-8, and Article 9 investigated? Are they subject to a complaint being made and maintained (Article 15)?

Yes.

In accordance with paragraph 2 of Article 140 of the Criminal Procedure Code of the Russian Federation, the basis for initiating a criminal case is the availability of sufficient data indicating signs of a crime.

The withdrawal of the complaint is not provided for by Russian legislation.

Article 76 of the Criminal Code of the Russian Federation allows, by court decision, exemption from criminal liability in connection with reconciliation with the victim for persons who have committed a minor or moderate crime for the first time and have made amends for the harm caused to the victim. The offences provided for by the Convention are classified as

moderate or severe, and in practice, the termination of a criminal case in connection with the reconciliation of the parties for the aforementioned offences does not apply.

Question 33. (optional)

In relation to counterfeit medical products and similar crimes involving a threat to public health, is there an indicative list of offences, associated with Articles 5-9, 11 and 13 and other criminal laws, to facilitate investigators in deciding the legal basis and the evidence required for successful investigations, in particular during a pandemic when advisory experts and technical staff may not be immediately available (Article 16)?

Question 34. (optional)

Please outline the national approach with regard to investigating bodies/authorities on counterfeit medical products and similar crimes, in a manner consistent with procedural rules of internal laws, on the extent of any discretion on whether to initiate and terminate an investigation without reference to a prosecuting authority or other investigating authorities for medical product counterfeiting?

Sanctions and aggravating circumstances

This section aims at identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating offences committed in a pandemic.

Question 35. (mandatory)

Do internal laws permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8? (Article 12. 2. a and b).

In accordance with Part 19 of Article 38 of Federal Law № 323-FZ, falsified medical devices and substandard medical devices are subject to withdrawal from circulation and destruction on the basis of the decision of the owner of the medical device, the decision of the authorized federal executive authority exercising control and surveillance functions in the field of health safety, or a court decision.

The rules for the destruction of seized falsified, substandard and counterfeit medical devices are approved by the Decree of the Government of the Russian Federation of September 15, 2020 № 1440.

The decree of the Government of the Russian Federation "On approval of the procedure for the withdrawal from circulation and destruction of falsified medical devices, substandard

medical devices and counterfeit medical devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval.

In accordance with Part 6 of Article 47 of Federal Law № 61-FZ, falsified, substandard medicines are subject to seizure and subsequent destruction or shipment from the Russian Federation, counterfeit medicines - to seizure and subsequent destruction.

In accordance with Part 1 of Article 59 of Federal Law № 61-FZ substandard, falsified medicines are subject to withdrawal from circulation and destruction in the order established by the Government of the Russian Federation. The basis for the destruction of medicines are the decision of the owner of the medicines, the decision of the relevant authorized federal executive authority, or a court decision.

The rules for the destruction of seized falsified, substandard and counterfeit medicines, were approved by the Government of the Russian Federation dated September 15, 2020 № 1447.

In accordance with the first part of Article 81 of the Code of Criminal Procedure, any items are recognized as material evidence: which served as instruments, equipment or other means of committing a crime or retained traces of a crime (paragraph 1); to which the criminal acts were directed (paragraph 2); other objects and documents that can serve as means for detecting a crime and establishing the circumstances of a criminal case (paragraph 3).

As a general rule material evidence should be kept in a criminal case until the sentence comes into legal force or until the expiration of the appeal period against a decision or ruling to terminate a criminal case and be transferred along with the criminal case.

Within the framework of a criminal case, falsified medical products, active pharmaceutical substances, implements, parts and materials, as well as other means used to commit a crime, may be recognized as material evidence. In accordance with part 3 of Article 81 of the Criminal Procedure Code of the Russian Federation when a verdict is passed as well as a ruling or order to terminate a criminal case the issue of material evidence must be resolved. Wherein:

instruments, equipment or other means of committing a crime, belonging to the accused, are subject to confiscation or transfer to the appropriate institutions, or destruction;

items prohibited for circulation are subject to transfer to the appropriate institutions or destruction.

Question 36. (optional)

Are there policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering, for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming?

Question 37. (optional)

Is there a policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products?

Question 38. (mandatory)

Is there a specific sanctioning policy relating to offences related to counterfeit medical products and similar crimes generally, with specific reference to Article 13 circumstances in so far as they do not already form part of the constituent elements of the offence, and if so, whether the fact that the offence occurred during a pandemic is considered as an aggravating circumstance?

In accordance with paragraph "L" of Part 1 of Article 63 of the Criminal Code of the Russian Federation an aggravating circumstance is the commission of a crime in a state of emergency, natural or other public disaster, as well as during mass riots, in conditions of an armed conflict or in case of war.

Question 39. (optional)

Please specify if and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article 13. c).

One of the criminal punishment provided (as an additional one), inter alia for the circulation of falsified, substandard and unauthorized medicines, medical devices and the circulation of falsified nutritional supplements (Article 238.1 of the Criminal Code of the Russian Federation), is deprivation of the right to hold certain positions and be engaged in certain activities, consists in the prohibition to hold positions in the public service, in local self-government authorities, or to be engaged in certain professional or other activities.

At the same time, by part 3 of Article 47 of the Criminal Code of the Russian Federation, deprivation of the right to hold certain positions or be engaged in certain activities can also be imposed as an additional type of punishment in cases where it is not provided for by the corresponding article of the Special Part of the Criminal Code of the Russian Federation as a punishment for the corresponding crime, if, taking into account the nature and degree of social danger of the crime committed and the personality of the guilty person, the court finds it impossible to retain his right to occupy certain positions or engage in certain activities.

Data Collection

This section concerns the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

Question 40. (optional)

Please indicate whether data is collected for the purpose of observing and evaluating the phenomenon of counterfeit medical products or for another purpose (Article 17.3.a and b). Please:

- a. Specify if data is collected in the normal course of activity and for what purpose.
- b. Indicate whether they were collected specifically during the COVID-19 pandemic. If not, can data for the period of the pandemic be separated from that collected in the normal course of activity?
- c. Specify what mechanisms have been established for data collection.
- d. Provide the relevant data collected, in particular that during the COVID-19 pandemic, and any reports from the analysis of this data.
- e. Indicate if the data and relevant reports based on such data were shared with all the relevant authorities/bodies. Please list the authorities/bodies that compiled the data, produced the reports and those who received them

The procedure for collecting and recording information about the falsification of medical products is described in detail in question 31.

As indicated in question 24, during the pandemic, medicines used to treat coronavirus infection were taken under special control. The results of selective control are also recorded in the automated information system of Roszdravnadzor.

These databases allow you to filter and search information by date, product name, so a separate analysis of the information obtained during the pandemic, including by individual product names, is possible.