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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

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by 30 November 2021

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)?

Answer: Legislative provisions related to counterfeits are set up for the healthcare field, particularly in the manufacturers, and distributors of medicines. However, there are no specific provisions for trainings in falsification of medical products in the law enforcement authorities, customs services, and justice.
Comment:

A) **Healthcare authorities:** In Armenia, the Good Distribution Practices of the European Union are established on 14 Jun 2017 by the Order of a Minister of Health № 32-N On adopting the rules of Good Manufacturing Practice for medicinal products, APIs, and for investigational medicinal products in the Republic of Armenia. The Order of the Minister is derived from the Article 24 of the Law on Medicines. The Good Distribution Practice establishes a chapter on Personnel where it is mentioned that the responsibilities of the responsible person of the distributor include deciding on the final disposition of returned, rejected, recalled, or falsified products. It is mentioned in the same chapter that training should include aspects of product identification and avoidance of falsified medicines entering the supply chain. In the Republic of Armenia, currently, there are more than 170 distributors and the implementation of the Good Distribution Practices is, currently actively being processed.
B) **Law Enforcement Authorities:** Legislation on law enforcement authorities is establishing that officers should be trained, however, there are no available specific

provisions on the topic related to falsification of medicinal products and similar crimes.

C) **Customs authorities:** Legislation on customs authorities establishes that customs officers should be trained, however, there are no specific provisions on the topic related to the falsification of medicinal products and similar crimes.

D) **specialized investigation units/bodies**: There are no established specific units or bodies in Armenia having purposes of investigating counterfeit medical products and similar crimes, in specialized techniques, including financial investigations. In 2012, 2016, and 2017 upon the initiative of the Scientific Center of Drug and Medical Technology Expertise (hereinafter SCDMTE), trainings on medical products and crimes set out in the Convention was imitated and organized with the support of international donors, including the Council of Europe.

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 for any deficiencies (Articles 18.1, 2, and 3. a)?

Answer: Partially, yes.

Comment: There are legally binding provisions for training and assessment of the effectiveness of the training for the personnel of the healthcare regulatory authority (SCDMTE) and distributors of medicinal products and the legal acts listed in the comments of Question 1. There are established several documents legally binding implementation of the Quality Management Systems for SCDMTE (such as the Quality Management System for national inspectorates under decision 82 of the Council of Eurasian Commission) within that, training effectiveness is required. Another requirement is again, for the manufacturers and distributors authorized in the Republic of Armenia. However, no legal act or provision provides a requirement neither Quality Management System implementation or training effectiveness assessment for other involved parties, such as law enforcement authorities or customs service.

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?

Answer:

Comment: In Armenia, it has been established the Decree of the Government of the Republic of Armenia N 164-N of February 28, 2019 On adopting the procedures in the Republic of Armenia related to rapid alert, termination of circulation and recall of nonregistered, non-conforming quality requirements, expired, registration withdrawal or suspended medicinal products, counterfeit medicinal products, active substance, herbal substances, investigational medicinal products, and medicinal products imported in violation

of the legislation of the Republic of Armenia. Based on this procedure awareness-raising process is raised in each case of detected counterfeit medical products in the Republic of Armenia and each detected case is reported to law enforcement authorities. However, the 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 are not involved directly.

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?

Answer: Yes
Comment: Currently, the disposal of medicinal products is regulated by Article 26 of the Law on Medicines of the Republic of Armenia. According to the Law, all medicinal products shall be destroyed by a licensed legal entity or sole entrepreneur under the requirements on the disposal of hazardous waste under the Republic of Armenia legislation and other legal acts. Hence, the disposal is done by only authorized entities.
Under the current law, the powers of the implementation of control over the circulation of drugs within its jurisdiction provided by the Law on Medicines belong to the Health and Labour Inspection body (See the Prime Minister's decision N 755-L of June 11, 2018 on approving the regulations of the health and labor inspection body of the Republic of Armenia).
At this stage, the Health and Labour Inspection body carries out oversight in the following follows: the customs services apply for the inspection of the drug - specifying the amount, the inspection gives a conclusion about the method and place of destruction, they destroy, the act is sent to the inspection
The Governing Council of the Health and Labour Inspection Body adopted the procedure for accepting complaints received from the public and their further processing in the field of activity of the Health and Labor Inspection Body of the Republic of Armenia.
For the future, the draft amendment to the Law on Medicines is currently being elaborated. It envisages provisions aimed at regulating the disposal and including the regulations that the Health and Labour Inspection body will play a role in the disposal process.

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.

Answer: There are no peculiar provisions for pandemics
Comment:

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.
Answer: No
Comment: It has not been elaborated strategy or policy of other measure by the government and, currently, it is not planned yet, to educate the public on risks associated with counterfeit medical products, in particular those that may be encountered during a pandemic. However, awareness-raising activities fragmentally are exercised by the Health and Labour Inspection body through their webpage.

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.
Answer: No
Comment: Several universities, such as Yerevan State University, Yerevan State Medical University, Russian-Armenian University, and other private universities, prepare future specialists in the respective fields of Pharmacology and Pharmaceutical Sciences. In those universities syllabuses of several courses contain outcomes related to crimes of medical products. A special course on Drug Law at Russian Armenian University is offered within the Health Law Master Program where dedicated topics are designed for the topics of counterfeiting and Medicrime Convention. Cooperation is enhanced by meeting with the students of academic institutions initiated by the SCDMTE to promote discussion and awareness among students on the issues covered by the Convention. A recent example is the meeting at the French University in Armenia.

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.
Answer: No
Comment:

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)?

Victims

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

Answer: The Law on Medicine sets requirements for information dissemination about medicine (Article 27) and for advertisement (Article 28). Those provisions are prohibitive but not prescriptive to proactively inform the public at large about counterfeit medical product.
Comment: Under Article 27, the goal of information on medicinal products is the safeguarding of their purposeful and effective use through providing credible information about them. For this purpose, shall be complete, impartial, and credible, justified with scientific research and/or data confirmed upon registration. The law contains specified regulations for medicinal products with and without prescriptions taking into account how the information is disseminated (media, or academic, scientific research, etc.) and providing prohibition of any advertisement elements in case of products without prescriptions. By the Law, disseminating information on medicinal products sold with a prescription in the mass media is prohibited.
Under the Law on Advertising, it is banned to advertise medications, medical equipment, and methods of medical treatment if a special medical prescription is needed for using those products. Permission to advertise medicinal products shall be issued by the Authorized Body under the procedure defined by the Government. Relations related to Medicine advertisements are also regulated by the Law on Medicines.
Article 28 of the Law on Medicine provides detailed regulation of the advertisement by different means, including online and mass media. It is prohibited to advertise medicinal products not registered in the Republic of Armenia, or medicinal products controlled in the Republic of Armenia or medicinal products prepared in a pharmacy according to a prescription or pharmacopeia.
Under the current law, the powers of the implementation of control over the circulation of drugs within its jurisdiction provided by the Law on Medicines belong to the Health and Labour Inspection body.
Code on Administrative offenses (Article 47.4) envisages administrative liability for violating the requirements for advertising of medical equipment, therapeutic methods, commercial (commercial) advertising of blood or its components donation and transfusion medical assistance or human organs and tissues.

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)?

Answer: Criminal Procedure Code of Armenia, Criminal Code of Armenia

Comment:

The new procedural concept of the victim significantly affected the content of his status. The victim can participate in the criminal proceedings both personally and through a representative. Depending on the features of the victim's personality, this representation may be mandatory or discretionary for him.

The fact that the damage suffered by the victim was directly caused by the alleged crime is no longer a mandatory condition for giving him such a status. This means that a victim can be recognized as a victim within the framework of criminal proceedings, either the person against whom the crime was directed or the person whose legal interests were not directly violated (for example, in the case of killing a person with the use of an explosive device, the victim will also be recognized as a victim person whose property damage was caused by that act).

According to Article 6 of the Criminal Procedure Code of the Republic of Armenia, the victim is a natural or legal person, state, community, or international organization, regarding which there are sufficient grounds to assume that the alleged crime caused damage to him or could have been caused if the alleged crime was completed. A similar definition is provided in Article 3 of the Criminal Code, according to which the victim of a crime is a person, organization, society, or state, whose rights, freedoms, or legal interests were harmed by the crime or could have been caused if the crime ended, regardless of the fact of being recognized as a victim in the judicial procedure.

The first part of Article 50 of the Code of Criminal Procedure specifies who makes the decision to recognize a victim (made by the investigator or the court), and the second part lists a non-exhaustive list of around three dozen rights, including **information-related rights** of the victim, which he can exercise during the trial. According to this, the victim has the right to: (1) get acquainted with the charge presented to the accused, (8) receive free of charge copies of the legal acts related to his status; (10) to get acquainted with the record of the evidentiary and other procedural action performed with his participation, to submit remarks regarding the accuracy and completeness of the entries in that record, to familiarize himself with the record of the court session and to submit his comments on it, to participate in the evidentiary and other procedural action, to request the appropriate record if present at the court session to make notes about the circumstances indicated by him, (11) to receive free of charge copies of decisions to initiate, not initiate, stop or suspend criminal prosecution, as well as to terminate criminal proceedings, a copy of the indictment, final act or final judicial act, (12) free of charge at his request to receive copies of the protocol of evidentiary and other procedural actions performed with his participation, including its appendix, as well as the decision to appoint an expert and the expert's opinion, (13) to familiarize himself with all the materials of the proceedings from the moment of receiving the notification of the completion of the preliminary investigation, to receive copies of them free of charge or out of them at his request to write any information, (14) to receive proper notice of the place and time of the court hearing.

Rights related to compensation are enshrined in the same second part of Article 50 of the Criminal Procedure Code which concerns (23) the damage caused by the crime; (24) expenses incurred for participating in evidentiary or other administrative action each time; (26) release from the obligation to pay for the services of his representative in the cases provided for by law; (27) to request and receive special protection from the body conducting the proceedings in the event of a threat to his life, health, and legal interests, as well as that of his family member or other close person.
Unlike the previous code, not listing the types of damage caused to the victim by the alleged crime makes it easier to recognize the victim in cases where it is not possible or at least controversial to identify the existing consequences with moral, physical or material damage.

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)?
Answer: the Criminal Procedure Code
Comment: The second part of the Criminal Procedure Code lists a non-exhaustive list of around three dozen rights that target the measures enshrined in Article 20.1 of the Criminal Procedure Law. One of the rights enshrined in Article 50 of the CPC, is to request and receive special protection from the body conducting the proceedings in the event of a threat to his life, health, and legal interests, as well as that of his family member or other close person. The Public Defender's Office, except providing legal aid to a person arrested or accused within the framework of criminal proceedings, as well as the cases specified in part 6 of this article, provides free legal aid provided in this article to the persons based on a variety of criteria, including poverty and social assistance (Parts 5 and 6 of Article 41 of the Law "On Advocacy").

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 proceedings and outside of proceedings concerning offenses related to counterfeiting of medical products and similar crimes involving a threat to public health? Please provide information on any such organizations and groups/bodies. Please provide information on any assessment of the effectiveness of such involvement by such providers (Article 20.5).
Answer:
Comment:

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.
Answer: No
Comment:

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).

Answer: A report about the alleged crime is a reason to initiate a criminal proceeding. It can be lodged in written or oral form. The direct report of a natural person is written in the first person. A postal communication by an individual must be in the form of a letter, e-mail or other accepted form of communication.
Comment: According to Article 173 of the Criminal Procedure Code of the Republic of Armenia, the investigator has a **duty to initiate criminal proceedings** within the limits of his jurisdiction, if the proper report on the alleged crime has been received from a natural person, a legal entity, the state or local self-government body or its official in connection with the implementation of its activities; the body carrying out operative-investigative activity, investigator, prosecutor or judge in connection with exercising his powers.
The information about the crime published in the mass media can also be a reason for the investigator to initiate criminal proceedings.
The oversight to assess the effectiveness of such measures upon the individual cases by the constitutional bodies - prosecutor and judiciary. The prosecutor exercises, inter alia, the oversight over the lawfulness of pre-trial criminal proceedings. By international law, the rejection of a request for the extradition of a person is an occasion to initiate criminal proceedings in connection with the alleged crime mentioned in the extradition request, if the Armenian Criminal Code applies to that person and the alleged act attributed to him. Criminal proceedings cannot be initiated if the information about the crime was received from a source not provided for by this article, including an unknown or undisclosed source.
When it comes to international cooperation in the investigation of transborder criminal cases, the draft law on legal aid in criminal cases is available for public discussion.

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).

Answer:

Comment: The legislation mandatory binding the exchange of information on counterfeit medical products are Decree of the Government of the Republic of Armenia N 164-N of February 28, 2019 «On adopting the procedures in the Republic of Armenia related to rapid alert, termination of circulation and recall of nonregistered, non-conforming quality requirements, expired, registration withdrawal or suspended medicinal products, counterfeit medicinal products, active substance, herbal substances, investigational medicinal products and medicinal products imported in violation of the legislation of the Republic of Armenia», the Government decree №199-N from 28 Feb 2019 of the Republic of Armenia "On adopting the rules of conducting GMP compliance inspection of manufacturers of medicinal products and active pharmaceutical ingredients, rules of issuance of Good Manufacturing Practice certificate, conducting an expertise on licensing of manufacturers of medicinal products and establishing the list of required documents, and, also, to recognize the loss of power of the Government decrees №1603-N from 15 Nov 2010 and 1089-N from 26 Sep 2013 and Decree of the Government of the Republic of Armenia N 156-N of February 28, 2019 «On adopting the rules of inspection in the scope of distributor certification and issuance a Good Distribution Practice certificate, the assessment rule for the purpose of licensing the medicinal products wholesale realization and the list of necessary documents in the Republic of Armenia». The Decrees on inspection make making mandatory to inform to law enforcement authorities in case anything has been identified during the inspections related to the falsification of medicines.

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.

Answer: No
Comment:

Question 17. (optional)

Please state on cooperation arrangements which authority has the lead and which participates 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.

Answer:
Comment: Actually, the lead authority is not designated. Risk assessment to the public is performed by the Health authorities, particularly, by SCDMTE based on the Government Decree 164-N. The cases that are detected by law enforcement authorities are, usually, communicated with health authorities, based on the Criminal Code of the Republic of Armenia. In line with the N 202 Government Decision of 2019, each delivery of medicine is passed through the expertise of the Healthcare authorities which in practice complicates the process of importing or penetrating the medicinal product into the legal supply chain. This situation is also a condition by the mere fact that there are only three customs checkpoints throughout the country

Question 18. (optional)

Do any arrangements involve cooperation arrangements with civil society, with industry or with 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 as a result of a pandemic.

Answer: No
Comment:

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.
Answer:
Comment:

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.
Answer: Partially Yes
Comment: The SPOCs are identified based only on written correspondence between involved authorities. However, it has been initiated changes by Healthcare authorities to the Government decree establishing the terms of reference of SOPCs and the co-ordination of SPOC at both the national level and the exchange of information between the national SPOC and international partners.

Question 21. (optional)

Is there a point of contact specified for the international exchange of information relating to the counterfeiting of medical products, 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.

Answer: Partially Yes
Comment: The SPOCs are identified based only on written correspondence between involved authorities. However, it has been initiated the Government decree draft establishing that the terms of references of SOPCs and co-ordination of SPOC both national level and exchange of information between the national SPOC and international partners.

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?
Answer: No
Comment:

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?
Answer: Yes
Comment: Several legislative acts envisage the duty of industry to report suspicions or detections of counterfeit medical products and similar crimes involving threats to public

health to any authority, including mostly, healthcare authorities, and, also, law enforcement agencies. The legal basis serves Article 17 of the Law on Medicines dedicated to reporting of adverse reactions and falsified medicines. Paragraph 10 of the Article establishes that health sector specialists, entities involved in the circulation of medicinal products, consumers, and the registration certificate holder shall, under the procedure established by the Authorized Body, also inform the Authorized Body about the lack of efficacy of medicinal products, about wrong use, and suspected counterfeiting.
“Med safety” mobile application was created by Pharmacovigilance and founded by WHO which allows to submit a complaint to respective authorities about suspicions or detections of counterfeit medical products and similar crimes involving threats to public health.

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?
Answer: No
Comment:

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?
Answer: No
Comment:

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?
Answer: Yes
Comment: The Government decree № 202-N from February 28, 2019 «On establishing the procedure on importation into territory of the Republic of Armenia and exportation from the territory of the Republic of Armenia medicinal products, active pharmaceutical ingredients, herbal substances and investigational medicinal products, procedure on conducting expertise for importation and exportation and establishing required documents, also, to recognize the loss of power of the Government decree № 581-N from 20 Sep 2000» is establishing procedure that making mandatory of expertise each delivery of medical products to the Republic of Armenia. Expertise is including release of the conclusion from Healthcare authorities, which become a basis for customs clearance.

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

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)?

Answer:

a. Under the existing law, no general definition containing medical products and devices is envisaged. The medicinal products are regulated by separate Law on Medicine (Drug Law). Art 3 of the Law on Medicines contains the definition of medicinal products. The terms active substance and excipient are components of the dosage medicinal product. They are defined separately.

1.1) **The medicinal product**: any substance of human and/or animal and/or vegetable and/or chemical and/or biotechnological origin in an appropriate dosage and dosage form, and the requisite packaging and labeling, which presented as having properties for treating or preventing disease in human beings or animals or may be used in or administrated either to restore, correct or modifying physiological functions by exerting a pharmacological and/or immunological and/or metabolic action, or to making a medical diagnosis.

1.6) **Dosage form**: a form that has the complex profile of physical, chemical, and pharmaceutical features of the medicinal product, ensuring a diagnostic or preventive or treatment outcome, and issued suitably for use;

1.7) **Strength of the medicinal prod**uct: the content of the active substances expressed quantitatively in the measurement units established for each dosage form.

1.8) **Substance**: material of human origin (human blood, blood products, other materials of human origin), and/or material of animal origin (microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; and other materials of animal origin), and/or material of vegetable origin (microorganisms, plants, parts of plants, vegetable secretions, extracts; and other materials of vegetable origin), and/or material of chemical origin (elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis, and other materials of chemical origin); when used for preparing or manufacturing medicinal products, and having pharmaceutical or immunological or metabolic activity.

The term in Art. 3, § 1.8 is translated as “drug substance” and emphasizes the active substance of the element. It is also described in the definition. Besides, the word ‘active’ in the English version is missing which is present in the Armenian version. In the case of excipients, Art 3, § 1.10 literally provides “any ingredient that is not an active ingredient of the drug, or packaging material. (Please note that in the texts of Law on Medicine available on webpages there is an inaccuracy of translation: the word ‘active’ is missing in the English text which is present in the original Armenian version).

Medical devices are defined in Art 2 of the Agreement on common principles and rules for the circulation of medical devices (medical products and medical equipment) in the framework of the Eurasian Economic Union. (Please note that from 2020 to July of 2022all definitions related to medical devices was provided under the Law on Medical Aid and Service of the Population. Afterward, as Armenia is a member of the Eurasian Union, common principles and rules for the circulation of medical devices within the Union to form a common market of medical devices are regulated by the mentioned Agreement) The notions of Accessory (Art. 4.f) and Part and materials (Art. 4.g.) are included in the definition of medical devices.

> “ medical devices”- any instruments, apparatus, appliances, equipment, materials and other products, which are used for medical purposes alone or in combination with each other as well as with the accessories required for use of these products for intended purposes (including special software), intended by manufactures for conducting preventive measures, diagnosis and treatment, medical rehabilitation and monitoring of the human body, conducting medical research, rehabilitation, replacement and alterations of anatomical structure or physiological functions of organism, preventing or terminating of pregnancy and functionality, which cannot be realized by pharmacological, immunological, genetic or metabolic effects on the human body, however, can be supported by drugs.

Art 3, § 1.40 of the Law on Medicines defines a registration certificate. It is accordingly an official document confirming the fact that a medicine has been registered in the Republic of Armenia per the procedure stipulated by law. Besides, the term “accompanied” document is mentioned in the definition of counterfeit.

Art 3, § 1.18 of the Law on Medicines defines Manufacturing. It is serial release activities involving either procurement of raw materials or manufacturing processes or quality control or packaging or repackaging or labelling, relabeling or storage or batch release and related controls. For medical devices, the definition provided in Article 2 of the EAU agreement contains the notion of circulation.

b. The definition of counterfeit is provided in the Art 3, § 1.15 of the Law on Medicines: A product which is deliberately and fraudulently mislabelled with respect to identity (including the packaging, labeling, name, composition, and quantities of individual ingredients) and/or source (including the manufacturer, the production country, the country of origin, and the registration certificate holder) and/or distribution chain (including protocols and accompanying documents).
c. The new Criminal Code of Armenia which was adopted in May of 2021 came into legal force on July 1, 2022. The new code implemented the conventional provisions set out in Articles 5 and 6.
   Article 5 corresponds to Art. 408, §1 of the Criminal Code (entitled Illegal circulation of drugs, medicinal substances, herbal raw materials, excipient, medical products or investigational pharmaceutical products) that contain preparing, manufacturing, storing, transporting, shipping, importing, exporting, supplying, offering to supply, putting on the market or selling a drug, drug substance, herbal raw material, excipient, medical product, their parts or researched pharmaceutical products for sale.
   Article 6 corresponds to Art. 409, §1 of Criminal Code (entitled Circulation or sale of counterfeit alcoholic beverages, baby food, biologically active supplements, drugs, medicinal substances, herbal raw materials, auxiliary substances, medical products or investigational pharmaceutical products for sale) that contain preparing, manufacturing, storing, transporting, shipping, importing, exporting, supplying, offering to supply fake alcoholic beverage, baby food, biologically active supplement, drug, medicinal substance, herbal raw material, auxiliary substance, medical product, their parts or investigational pharmaceutical product for sale, marketing or selling them/

d. Art 8 of the Convention dedicated to similar crimes involving threats to public health provides the duty to take necessary legislative and other measures to establish as offenses… committed intentionally. Although the Medicrime Convention contains requirements only about ‘offices committed intentionally’ it does not prohibit the states to set out liability for offenses committed with other forms of guilt if that liability meets the requirement of the proportionality test.

   Art 8.a.i of the Convention (‘medicinal product without authorization’) corresponds to Articles 408 and 409 of the Criminal Code. It is criminally punished to prepare, manufacture, storing, transport, ship, import, export, supply, offer to supply, place on the market, or sell them for the realization of the drug, drug substance, herbal raw material, excipient, medical product, parts thereof or investigational pharmaceutical product without state registration provided for by law or under the conditions of registration suspended, terminated or revoked by the law, without registration or special permission (license).

   Art 8.a.ii of the Convention (Manufacturing … medical devices without complying with the conformity requirements) is covered by Article 408 of the Criminal Code. Besides, Art. 46

Law “On Medical Aid and Service of the Population” provides that only authorized medical devices are allowed except for the cases set out in Art 46§1.

Art 8.b of the Convention (the commercial use of original documents outside of their intended use) is covered by Art. 411 of the Criminal Code dedicated to the Illegal use of genuine documents certifying the identity of drugs, medicinal substances, herbal raw materials, excipient, medical products, or investigational pharmaceutical products.

e. Art 7 of the Convention (Falsification of documents) is reflected in Articles 410 and 411 of the Criminal Code. Art. 410 sets prohibitions relating to making or using false documents certifying the identity of counterfeit alcoholic beverages, baby food, biologically active supplements, drugs, medicinal substances, herbal raw materials, excipients, medical products or investigational pharmaceutical products, and Art. 411 concerns prohibitions related to Illegal circulation of genuine documents certifying the identity of drugs, medicinal substances, herbal raw materials, excipient, medical products or investigational pharmaceutical products.
f. This is the novelty of the Criminal Code that previously did not envisage legal liability for legal entities. For the first time, the Armenian Criminal Code envisages legal entities liable for criminal offenses (Article 19§1). General rules of criminal liability of legal entities and sanctions are specified in Chapters 20 and 21 (Articles 122-132). Besides, the criminal liability of a physical person does not exclude the liability of a legal entity.

Comment:

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.

Answer: No
Comment:

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).

Answer: No
Comment: There are two possible scenarios: one is when the medical product is imported, and the other is when the product is identified in the market. When the products are imported the customs service must check whether the product is registered or authorized to be imported. Other than that they can report to the competent authorities about the suspicious on the offenses. The second case is when the product is on the market. In that case, the detection of offenses could be exercised through two processes: complaint received by the consumer or competitor either a market sampling programme.

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 a facility.

Answer: Yes,
Comment: Reporting is done by telephone, email, via an online platform, or other means, and this is a confidential report system.

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?

Answer: Yes
Comment: Healthcare authorities are responsible for record keeping, analysis, and effective investigation in terms of public health.

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)?
Answer: Yes.
Comment:

Articles 408-411 of the Criminal Code of the Republic of Armenia Articles 408-411 contain provisions set out in Articles 5-8.

The content of Article 9 of the Convention is reflected in the articles Art. 46 of the Criminal Code (Types of complicity in crimes), Art. 42 of the Criminal Code (Completed and uncompleted crimes), and Art. 44 (Criminal attempt and its types).

The requirement set out in Article 15 of the Convention is healthcare laws and criminal code, based on which the investigative bodies should be informed by the respective authorities on the mere fact of violations regardless of the fact of having received a complaint. Hence, the initiation and course of the investigation of criminal cases are not subject to complaints.

When it comes to the provision of Article 15 of the Convention, the Armenian criminal legislation envisages that investigation of all types of crime are not subordinate to complaints except for the list of crimes provided in article 15 of the Criminal Code. The crimes similar to the offenses set out in the Convention are not among those crimes.

Hence, when the victim is classified as a group of persons who require additional attention or are vulnerable, the need to protect the countervailing interest makes it necessary to ignore the possible free will of the victim both in the matter of starting and continuing the proceedings, as a result of which the prosecution is initiated and carried out in public order, including both pre-trial, as well as judicial procedures.

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)?
Answer: No
Comment:

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?

Answer: Investigations and prosecution are performed based on criminal proceeding legislation without any exceptions or extent related to medical products.
Comment:

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).

Answer: Yes

Comment: See the comments provided for Questions 3 and 4 of the present Questionnaire.

Question 36. **(optional)**

Are there policies facilitating the prosecution of offenses 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?

Answer: Articles 5-9 are implemented generally only

Comment:

According to Article 47.3, violating the requirements of the field of drug circulation is considered an administrative offense. Administrative liability arises in the following cases:

- Importing, manufacturing, storing, or distributing drugs that are not registered in Armenia (except for cases defined by legislation) or whose registration has been suspended per the law, or violation of the law,
- Producing, importing, selling, storing, or distributing medicines, herbal raw materials, researched pharmaceutical products in violation of the law,
- Filling, issuing, and selling prescriptions for prescription drugs on forms not provided for by the legislation of the Republic of Armenia,
- Non-reporting of recorded cases of harmful side effects of registered drugs by the right holder of the drug registration certificate or publishing information about them without first or simultaneously notifying the authorized public administration body in the field of healthcare, etc.

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?
Answer: No any policy was envisaged that were publicly available.
Comment:

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?

Answer: Yes
Comment: The criteria and circumstances aggravating the punishment for committed crimes are provided by the Criminal Code (See below.).

Art 13 Aggravating circumstances		
Art 13.a	Fully corresponds Criminal Code Art 408, § 2, 1) Art 408, § 3 Art 409, § 2, 1) Art 409, § 3	Art 408, § 2, 2) covers negligently causing moderate or slight harm to human health. Art. 408, § 3 covers negligently causing death or serious damage to health. The offences that caused the death intentionally covered by Chapter 23 of the Criminal Code. Damages caused to health are covered by Chapter 24 of the Criminal Code, namely: Art.166 - Causing serious damage to health Art. 167 - Causing moderate damage to health Art. 172 - Negligently causing serious damage to health Criminal actions will be qualified considering the rules of combination of crimes.
Art 13.b	Fully corresponds Criminal Code Art 408, § 2, 2) Art 409, § 2, 2)	Art 408, § 2, 2) committed by abusing the trust formed in connection with the performance of the criminal's professional or official duties or acting as a producer or supplier Art 409, § 2, 2) committed by abusing the trust formed in connection with the performance of the criminal's professional or official duties or acting as a producer or supplier
Art 13.c	Fully corresponds	[Crime] committed by abusing the trust formed in connection with the performance of the criminal's

	Criminal Code Art 408, § 2, 2) Art 409, § 2, 2)	professional or official duties or acting as a producer or supplier
Art 13.d	Fully corresponds Criminal Code Art 408, § 2, 3) Art 409, § 2, 3)	[Crime] manifested in such a way as to ensure mass supply, its offer or realization
Art 13.e	Fully corresponds Criminal Code Art 50 § 5 **Committing crime by a group of persons or a criminal organization** Art. 71, § 1, 2) Circumstances aggravating criminal responsibility or punishment	Art. 50, § 5. A member of a criminal organization is subject to criminal liability for participating in a criminal organization, as well as for the crimes he participated in the execution or its preparation. 1. Circumstances aggravating criminal responsibility or punishment are: 2) committing the crime as part of a group or criminal organization
Art 13.f	Fully corresponds Criminal Code Art. 71, § 1, 1) Circumstances aggravating criminal responsibility or punishment Art. 318 **Creating or leading a criminal organization** Art. 319 **Participating in a criminal organization**	Art 71 1. Circumstances aggravating criminal responsibility or punishment are: 1) committing the crime by a person with a conviction

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 (Article13. c).

Answer: The New Criminal Code

Comment:

The new criminal code considers restoring social justice and preventing crimes as the goals of punishment, but instead of correcting the punished person, it sets a more realistic goal: resocializing the punished person.

In the new criminal code, the punishment system has undergone substantive and structural changes. New types of punishment were envisaged, for example, restriction of freedom, expulsion of a foreign citizen from the territory of Armenia, the names of individual types of punishment were changed (for example, detention was renamed to short-term imprisonment), most of the other preserved types of punishment were subject to changes (for example, although the type of punishment was preserved), but a fundamental change has taken place in terms of the basis of its calculation. If in the former criminal code the basis for calculating the fine was the minimum wage, then in the new criminal code it is the income of the person found guilty of the crime.

The punishment system has also changed the rotation of the types of punishment, which is of great importance, for example, when replacing the punishment with a milder punishment or when imposing a milder punishment than the one prescribed by law. If in the previous criminal code, the penalty was mentioned first, then in the new criminal code, the deprivation of an honorary or military title, order, rank, qualification class or state award. The punishment system is built on the logic that each subsequent type of punishment is more severe than the previous one. It is no accident that the penal system ends with life imprisonment.

The punishment system in the new Criminal Code has the following form:

1) deprivation of an honorary or military title, order, rank, qualification class or state award,
2) the fine,
3) public works,
4) to occupy certain positions or engage in certain activities
disenfranchisement
5) expulsion of a foreign citizen from the territory of the Republic of Armenia, 6) limitation in military service,
7) restriction of freedom,
8) short-term imprisonment,
9) detention in the disciplinary battalion,
10) imprisonment,
11) life imprisonment.

The system of criminal legal intervention measures applied to legal entities are the following: 1. fine, 2. temporary suspension of the right to engage in a certain type of activity, 3. forced liquidation, 4. ban on carrying out activities in the territory of Armenia.

Temporary suspension of the right to engage in a certain type of activity is a ban on engaging in a certain type or several types of economic, including entrepreneurial, or other activity for a period of 2 months to 2 years. Itis prescribed for the type of activity in the course of which the crime was committed or the crime was connected with its implementation. If the crime was related to several types of activity, the court temporarily suspends the right to engage in the type of activity that was directly related to the commission of the crime. It should not be prescribed if it will directly lead to the bankruptcy of the legal entity. In case of avoiding the temporary suspension of the right to engage in a

certain type of activity, it is replaced by forced liquidation. The temporary suspension cannot be assigned to a legal entity operating in the regulated sphere of public services, as well as to those legal entities whose activity is terminated by a special procedure established by the Constitution or other legal acts. More than one criminal-legal intervention measures may be imposed on a legal entity.

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.

Answer:
Comment:
a) each case of detected case of counterfeit medicine is approved by conclusion of the SCDMTE (health authority) and it is archived, in some cases it is published.
b) it is collected regardless any pandemic or any other situation,
c) data collection is done by SCDMTE partially based on the Government Decree 164-N from 2019.
d) will be provided,]
e) the data is transferred to, mainly, to law enforcement authorities, however, the customs are not notified.