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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

medicrime@coe.int

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 1. The MMDA employees receive training based on the annual training plan, which includes trainings, seminars and meetings organized by international bodies such as: World Health Organization (WHO), Pharmaceutical Inspectorate Co-operation Scheme (PIC/s), European Directorate for the Quality of Medicines & HealthCare (EDQM) where are addressed issues of preventing falsified medicinal products from entering the legal supply chain.

To prevent the distribution of counterfeit medical products in the pharmaceutical market, all medicines manufactured in the Republic of Moldova, as well as those imported, undergo state quality control conducted by the Quality Control Laboratory of the Medicines and Medical Devices Agency (MMDA). Additionally, data is obtained through the Rapid Alert System in collaboration with the WHO and EDQM.

Conversely, employees of the Customs Service did not take part in the training aimed at preventing counterfeit medical products, including active substances, excipients, accessories, parts, and materials.

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)?

Answer 2. Following the external trainings, MMDA employees prepare a report in which are specified recommendations for advancement, methods of implementation, terms and responsibilities. The confirmation of the completion of tasks is monitored by the direct supervisor.

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 3. Currently, there are no approved or planned programs for awareness-raising and training. The disposal of medication is regulated by Order of the Ministry of Health No. 9 of 06.01.2006 "On the harmless destruction of medicines with expired expiry date, counterfeit, with quality deficiencies or without documents of origin (accompanying)". There is a Draft of Government Decision approving the Regulation on pharmaceutical waste management, which is currently under development.

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 4. According to the provisions of Order of the Ministry of Health No. 9 of 06.01.2006 "On the harmless destruction of medicines", all of the disposal activities of drug products is carried out by Medicines and Medical Devices Agency. Current method of disposal of pharmaceuticals is encapsulation/ inertization, the activity being managed by Disposal unit within the Medicines and Medical Devices Agency.

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.

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 6. The MMDA maintains a State Nomenclature of Medicinal Products that includes all approved/authorised medicinal products within the Republic of Moldova. This nomenclature provides detailed information about each authorised medicine, including approved instructions and packaging design. Employees of the MMDA play a crucial role by offering tangible information in identifying potential counterfeit products. During Good Pharmacy Practice (GPP) inspections, efforts are made to promote responsible purchasing behavior among the public, thereby encouraging the rational use of medical products.

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.

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.

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)?

Answer 9. There is in place a Regulation on the ethical promotion of medicinal products approved as per Government Decision no. 944/2018, which transpose art.1, title VIII and VIIIa of Directive 2001/83/CE.
The contravention legislation of the Republic of Moldova establishes the punishment for the act of "advertising and marketing of medicines not authorized for use, of medicines with expired date, as well as those without the document and / or information attesting the quality and without the name and address of the manufacturer", this being provided by article 77 of the Contravention Code.

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)?

Answer 10. The rights of the victim are stipulated in article 58 of the Criminal Procedure Code. However, there are no specific provisions related to protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic.

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)?

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).

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).

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 15. There are no official agreements in place among the competent authorities or plans to adopt. Each case identified by a competent authority is communicated to the relevant authority on an individual basis.

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.

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.

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 as a result of a pandemic.

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.

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.

Answer 21. The Pharmaceutical Control and Inspection General Department, along with the Quality Control Laboratory, are divisions of the Medicine and Medical Devices Agency (MMDA) designated as the primary contact for international information exchange concerning the counterfeiting of medical products, including product alerts and analytical reports derived from laboratory investigations.

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 22. Republic of Moldova does not have legislation to underpin the existing exchange of information or transfer and receipt of data and evidence between bodies/countries relating to counterfeit medical products. The Medicine and Medical Devices Agency implements European procedures, for example, The Compilation of Union Procedures on Inspections and Exchange of Information.

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 23. In accordance with the stipulations outlined in Order of the Ministry of Health No. 1400 of 09.12.2014 on the approval of the Rules of Good Distribution Practice of Medicines (GDP) for human use, “Wholesale distributors are required to promptly notify the relevant authority and the holder of the marketing authorization of any medicinal products they recognize as counterfeit or suspect may be counterfeit”. Order of the Ministry of Health No. 1400 of 09.12.2014 transpose the 2013/C 343/01 European Commission Guidelines and partially transpose art. 85b of Directive 2001/83/EC. The responsible authority for receiving and processing the alerts regarding suspicions or detections is Pharmaceutical Control and Inspection General Department of the Medicine and Medical Devices Agency (MMDA).

Following the information provided by the industry and/or the marketing authorization holder, the MMDA makes a decision and publishes an official Order regarding the withdrawal of the medicine.

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 24. In accordance with the stipulations outlined in Order of the Ministry of Health No. 521 of 01.06.2012 on state quality control of medicinal products subsequent selective state control involves laboratory analysis that adheres to the standards of the chosen medicinal products, ensuring quality oversight and preventing the introduction of non-compliant products into the pharmaceutical market. All medicinal products available in the pharmaceutical market of the Republic of Moldova undergo subsequent selective state control according to a MMDA plan. In recent years, the market sampling programme has not been established and implemented due to the increased demands on the Quality Control Laboratory from the MMDA.

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 25. In accordance with the stipulations outlined in Order of the Ministry of Health No. 521 of 01.06.2012 on state quality control of medicinal products - “All medicines manufactured in the Republic of Moldova and imported medicines, the quality of which complies with the provisions of the monograph, are placed on the pharmaceutical market only with the presence of the documents: the "Quality Certificate" or the "Register of medicines, the distribution of which is authorized on the basis of quality certificates of the manufacturing plants and organoleptic control, packaging and marking", issued by the MMDA”. Medical products utilized within the public health system, such as hospitals, are required to undergo verification.

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 26. Customs Code nr.95/2021, article 425[12], paragraph (8): Expired medicines registered by the Customs Service are destroyed in the manner established by the Ministry of Health.
With reference to goods likely to infringe an intellectual property right, must be consulted the Chapter IV (Title IX) "Measures for the protection of intellectual property" of the Customs

Code no. 95/2021 and the Implementing Regulation of the Customs Code no. 95/2021, approved by Government Decision no. 92/2023.

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)?

Answer 27.

a. The Penal Code (No. 985 of 18.04.2002) determines the object of the criminal offence without mentioning directly the term "medical product". It address the term "product", bearing in mind the definitions provided national organic laws (*Law No. 1409 of 17.12.1997 on medicines and Law No. 102 of 09.06.2017 on medical devices*) mentioned bellow. According to *Article 3, Law No. 1409 of 17.12.1997 on medicines* the term "medicines (medicinal products)" is defined as "substances or combination of substances authorized, in the prescribed manner, for manufacture, import, export and use, to treat, alleviate, prevent, diagnose a disease, an abnormal physical or mental condition or their symptoms in humans, or animal, as well as to restore, correct and modify their organic functions"
b. In the legislation of the Republic of Moldova, the term "counterfeit" is also used, which corresponds to that one set out in Article 4 letter (j) of the Convention, ie "a false representation as regards identity and/or source". The given term is found in the provisions of article 214^1 of The Penal Code, "Production or sale of counterfeit medicine."

c. The provisions of article 5 ”Manufacturing of counterfeits” of the Convention are found in article 214[1] of The Penal Code, "Production or sale of counterfeit medicine", in the standard version that is manifested by the manufacture or sale of counterfeit medicines, including the aggravating variant, provided in para. (2) of this article, which establishes the punishment for recklessly causing serious or moderate injury to health or death of the person as a result of the crime.
d. The provisions of articles 6 and 8 of the Convention are reflected in the text of article 216 of The Penal Code ” Production, transportation, storage, marketing, supply of products (goods) by onerous title or free of charge, provision of services dangerous to the life and health of consumers.”
e. Considering the provisions of article 7 of the Convention, the actions of falsification of documents described above are reflected in the text of article 361 of the Penal Code of the Republic of Moldova "Manufacture, possession, sale or use of official documents, printed materials, stamps or false seals".
f. In article 11 of the Penal Code of the Republic of Moldova "Application of criminal law in space" foresees jurisdiction over all offenses provided in this code.

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 28. The Customs Service investigates criminal cases based on articles 248, 249 of the Criminal Code of the Republic of Moldova (smuggling and evasion of customs duties). Accordingly, medicinal products and their analogues are classified as goods. During the investigation, the officers of the Customs Service verify the legality of the introduction of medicines by several methods (documents of origin, import authorisations, etc.). In the absence of such documents, if the amount of medicines (goods) exceeds 8000 conventional units (c.u.), a criminal case of smuggling is initiated (Article 248 of the Criminal Code of the Republic of Moldova). Should the quantity not surpass 8000 c.u., a contravention case will be initiated. In both cases, the goods will be confiscated and are subject to destruction.

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).

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.

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?

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)?

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?

Answer 34. The Customs Service does not document cases of counterfeiting or manufacturing of medicines on the territory of the Republic of Moldova. In cases where they have been illegally introduced into or removed from the country, the officers of the Customs Service document it as a smuggling offense or contravention. Throughout the case documentation process, the medicines may undergo examination to ascertain their authenticity.

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 35. Based on Article 248[1] of the Criminal Code of the Republic of Moldova, if the goods were introduced through smuggling and there are no documents of origin, and it is established after examination that the goods are counterfeit, they shall be confiscated and destroyed.

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?

Answer 38. The aggravating circumstances, which are provided for the establishment of the punishment, are regulated in article 77 of the Penal Code and are taken into account when individualizing the punishment for all offenses provided by the Penal Code of the Republic of Moldova.

In article 214[1] of the Penal Code, “Production or sale of counterfeit medicines”, the aggravated variant, provided in para. (2) of this article, involves recklessly causing serious or moderate injury to health or death of the person as a result of committing this act.

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).

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.