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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.

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*

[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.

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)?
   Order of the Ministry of Health of Ukraine dated 25 July 2023 № 1347 *"On approval of the List of specialisation cycles and thematic improvement in medical and pharmaceutical (pharmacy)*"
b. healthcare practitioners, police, customs, and health product regulators?
   Resolution of the Cabinet of Ministers of Ukraine of 14 July 2021 No. 725 *"On Approval of the Regulation on the System of Continuous Professional Development of Healthcare Workers"*
c. specialised investigation units/bodies in the investigation of counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?
   In Ukraine, there are specialised institutions and programmes that provide training on methods of investigating fraud using financial monitoring:
   The State Institution of Postgraduate Education - Academy of Financial Monitoring provides training for employees of primary financial monitoring entities and public authorities. The programmes include advanced training in financial monitoring and anti-money laundering.

   The central executive body implementing the state policy in the field of financial monitoring is the State Financial Monitoring Service of Ukraine conducts typological studies and provides methodological recommendations on detection and investigation of financial crimes.

   Shupyk National University of Healthcare of Ukraine: Continuing professional development courses for pharmacists and doctors, which include sections on medicines falsification. Faculties of Pharmacy at universities (Lviv, Kharkiv,

Kyiv): Teach disciplines related to quality control of medicines and methods of detecting falsification.

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)? Yes
SOP-10 *Staff training*
Registers of events are kept, and feedback from participants is collected.
Monitoring data is used to update training materials.
Identify bottlenecks and address shortcomings through revision of methodologies.

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? Yes
Order of the Ministry of Health of Ukraine No. 1602 dated 06.09.2022 '*On Approval of Amendments to the State Sanitary and Epidemiological Rules and Regulations on Medical Waste Management'*, art. 4. Employees are not allowed to work with waste without education, training and knowledge testing (hereinafter - training) on SOPs, depending on the involvement (performance of waste management processes by employees). The training must include SOPs on the algorithm of actions in case of emergencies. Art. 15 'The head of the facility ensures the availability and stock of PPE and organises training of employees on their use in the workplace in accordance with the Minimum Safety and Health Requirements for the Use of Personal Protective Equipment by Employees in the Workplace, approved by the Order of the Ministry of Social Policy of Ukraine No. 1804 dated 29 November 2018. Training is conducted on a scheduled basis at least once a year and on an unscheduled basis if necessary (for example, when a new SOP is introduced in the institution, in case of emergency).

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? Order of the Ministry of Health of Ukraine No. 1602 dated 06.09.2022 "*On Approval of Amendments to the State Sanitary and Epidemiological Rules and Regulations on Medical Waste Management"*, art Article X. Accounting of medical waste 1. Accounting, monitoring and informing in the field of medical waste management shall be carried out in accordance with the requirements of the legislation.2. The institutions shall draw up acts of waste transfer in the form given in Annex 6 to these Rules to the carrier or business entity that has obtained the Licence. 3. The facilities shall notify the territorial body of the central

executive authority, which carries out state supervision (control) over compliance with the requirements of the legislation on waste management at the place of operation, via the electronic communication network, of the transfer of waste to the carrier or business entity that has obtained the Licence, not later than 12 hours before the transfer in the form given in Annex 6 to these Rules. The Public Health Centre and the Ministry of Health have developed training webinars on Medical Waste Management.
ttps://www.youtube.com/playlist?list=PLiUQ4J0vu34p4dMuvP2JoQbLquVvZJjAF

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.

- Introduction of certification for masks and other PPE
- Control of the supply chain through registers of official manufacturers
- Detecting and destroying counterfeit consignments through cooperation between customs and law enforcement
- Tests for the diagnosis of COVID-19
- Introduce clear regulations on the validation of test systems (e.g. WHO has created a list of approved tests)
- Conduct educational campaigns for healthcare professionals on how to recognise low-quality tests
- Vaccines Introduction of unique identification numbers for each batch of vaccines.
- Use of cold chain technology for transportation, which allowed for the tracking of legitimate batches
- Training of medical staff on proper storage and recognition of counterfeits. 4. Antiviral drugs Control of imports and exports of drugs such as remdesivir and favipiravir
- Information campaigns on purchasing medicines exclusively from licensed pharmacies.
- Setting up hotlines to report suspicious medicines.

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; COVID-19 Information campaign “Trust but verify”: the Ministry of Health of Ukraine disseminated information about certified vaccines and testing systems. The introduction of chatbots and hotlines, which

allowed citizens to check the legitimacy of medical products.Educational materials and resources. Videos and infographics: How to recognise counterfeit medicines and where to check their registration status.
Educational seminars and trainings for healthcare professionals and citizens in the regions. Expanding access to official sources: For example, through the state portal with information on registered medicines.

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;
National information programmes:
Governments have launched information campaigns through television, radio, social media, and print media to warn citizens about the risks of purchasing medical products from unverified sources.
For example, in Ukraine, the Ministry of Health launched campaigns that focused on checking the registration of drugs in the State Register of Medicines. During the COVID-19 period, many campaigns were aimed at raising awareness of the risks of counterfeit vaccines, masks, disinfectants and tests.

c. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.
Information on detected and banned substandard, falsified and unregistered medicinal products is communicated to the population of Ukraine by posting online on the official website of the State Service of Ukraine on Medicines and Drugs Control (www.dls.gov.ua) and publishing relevant orders. The website also contains contact numbers of the responsible persons for the quality of medicinal products, which citizens can use to contact the State Service of Ukraine on Medicines and Drugs Control in case of doubt about the quality of medicinal products.

Are there any reports on the results of these measures? If so, please attach them to your responses to this questionnaire.
The National Agency for the Prevention of Corruption (NAPC) has published an analytical report on the results of the assessment of corruption risks in the procurement of medicines and medical products caused by the pandemic. The report contains recommendations to minimise such risks and increase transparency of the procurement process. The Accounting Chamber of Ukraine conducted an audit of customs clearance of medical devices during the pandemic. The report dated 19 December 2023 revealed cases of unjustified tax benefits and violations during the import of medical devices. This indicates the need to strengthen control over the import of medical products to prevent counterfeiting

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.

Yes. In accordance with the Resolution of the Cabinet of Ministers of Ukraine No. 996 "*On Ensuring Public Participation in the Formation and Implementation of State Policy"* dated 03.11.2010, Public Councils have been established and are functioning at central executive authorities,

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.

Yes. National media projects:

Civil society organisations, together with the Ministry of Health and the WHO, have conducted campaigns to combat counterfeiting. Examples: TV and social media spots urging people to buy medicines only from official pharmacies.

Local initiatives:

Civil society organisations provided training for healthcare professionals, pharmacists and citizens on how to recognise counterfeit medicines.

For example, the Safe Medicines for Everyone initiative included a series of trainings in cooperation with the WHO and the Ministry of Health of Ukraine. NGOs have been involved in the development of legislative initiatives aimed at strengthening the fight against counterfeiting.

Example: Cooperation of the NGO 'Patients of Ukraine' with the Ministry of Health in the implementation of drug labelling.

Organisations such as the WHO and the European Medicines Agency support local CSOs by funding educational projects. Civil society is actively using Facebook, Instagram and other platforms to disseminate information, including recommendations on how to buy medicines only from licensed pharmacies. Warnings about fraudulent schemes on the Internet.

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)?

The advertising of medicinal products is governed by:

- Article 87 of the Law of Ukraine "*On Medicinal Products*" (No. 2469-IX, July 28, 2022) "Advertising of medicinal products, the use and sale of which is permitted only upon a doctor's prescription, as well as those classified as prohibited for advertising, is prohibited".

The requirements for advertising of medicinal products shall be established by the Law of Ukraine *"On Advertising"* with due regard to the specifics defined by this Law. The criteria used in determining the medicinal products whose advertising is prohibited, as well as the procedure for making a decision and amending it, shall be approved by the central executive body responsible for the formation and implementation of the state policy in the field of healthcare in accordance with the requirements of this Law. The decision to classify a medicinal product as a medicinal product whose advertising is prohibited shall be made during the state registration (re-registration) or amendment of the registration materials of the

medicinal product with the relevant information entered into the State Register of Medicinal Products.

- Order of the Ministry of Health of Ukraine No. 422 (June 6, 2012): *"On Certain Issues Regarding the Prohibition of Advertising Medicinal Products"*, which specifies criteria for determining medicinal products whose advertising is prohibited until compliance with the updated Law of Ukraine *"On Medicinal Products"* is achieved.
- Article 21 of the Law of Ukraine *"On Advertising"*, which outlines requirements, restrictions, and warnings concerning the advertising of medicinal products.

Resolution of the Cabinet of Ministers of Ukraine No. 301-r dated 3 April 2019 *"On approval of the Concept for Implementation of the State Policy on Prevention of Counterfeiting of Medicines and Approval of the Action Plan for its Implementation"*.

- During the pandemic, Ukraine stepped up monitoring of e-commerce and social media. As a result, websites advertising counterfeit medicines or protective equipment were blocked.
- Online pharmacies are required to obtain licences and post them on their websites. This allows customers to check the legitimacy of the platform.
- During the pandemic, penalties were introduced for advertising or selling unregistered medicines that are offered as 'COVID-19 medicines.
- There is criminal liability for the dissemination of deliberately false information that may harm the health of citizens.

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)? Yes

The Criminal Code of Ukraine Article 321[1] of the CCU provides for criminal liability for the production, storage, purchase, transportation, shipment or sale of counterfeit medicines.

Victims of such crimes have the right to apply to law enforcement authorities to protect their rights and receive compensation.

The Law of Ukraine *"On Medicinal Products"*: Regulates the circulation of medicinal products in Ukraine and defines liability for violations related to their falsification.

Defines safety requirements for patients and mechanisms for recalling dangerous drugs.

The Law of Ukraine *"On Consumer Protection"*: Provides for recourse to the courts or state supervisory authorities to compensate for damages caused by counterfeit medicines.

Law of Ukraine *"On Free Legal Aid":* Victims of crimes, including counterfeiting of medical products, can benefit from free legal aid, especially if they belong to vulnerable groups.

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)? Yes
The victim has the right to file a criminal complaint, which obliges law enforcement agencies to initiate an investigation. Victims in such cases have the right to demand Independent expert examinations, compensation for damages from manufacturers or distributors of counterfeit products.

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). The system of free legal aid is a state network of legal aid access points throughout Ukraine and channels for obtaining legal services by phone and online.

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. No

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).

Regulation of the Cabinet of Ministers of Ukraine dated 3 April 2019 No. 301-r "On Approval of the Concept of Implementation of the State Policy on Prevention of Medicinal Products".

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)?

The Rapid Alert System is designed to deal with the threats associated with substandard medicines and recall them from the market. Information is received from consumers, patients, manufacturers, the Ministry of Health of Ukraine, the State Enterprise 'State Expert Centre', customs, national police, PIC/S member countries, WHO.

в. 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? Yes. The State Service of Ukraine on Medicines and Drugs Control signed memorandums of cooperation with the National Police of Ukraine, the Security Service of Ukraine and the State Border Guard Service of Ukraine to strengthen operational cooperation in resolving problematic issues and establishing a mechanism for exchanging information on detected and/or banned unregistered, imported into Ukraine in violation of customs regulations, substandard and counterfeit medicinal products.

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.

In order to promptly cooperate in resolving problematic issues and establish a mechanism for exchanging information on detected and/or banned unregistered, unauthorised, imported into Ukraine in violation of customs regulations, substandard and counterfeit medicines, the State Service of Ukraine on Medicines and Drugs Control has a permanent working group to track the distribution of counterfeit medicines, substances imported into the territory of Ukraine, the movement of used and decommissioned technological equipment that can be used for the production of counterfeit medicines, as well as counteracting illicit trafficking in medical devices, narcotic drugs, psychotropic substances and precursors. Thus, this group includes

representatives of, inter alia, the National Police of Ukraine, the Security Service of Ukraine, the State Customs Service of Ukraine, the State Border Guard Service of Ukraine and the Ministry of Health of Ukraine. Pursuant to Article 15 of the Law of Ukraine *"On Medicinal Products"*, the State Service of Ukraine on Medicines and Drugs Control sends letters to law enforcement and customs authorities regarding the facts of counterfeiting of medicinal products and/or illegal trade in medicinal products via the Internet.

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.

Ministry of Health of Ukraine: Policy development, coordination, regulatory framework.
State Service of Ukraine on Medicines and Drugs Control: Medicines quality control, inspection, licensing.
Ministry of Internal Affairs of Ukraine and State Security Service: Investigation of crimes, prevention of counterfeiting
State Customs Service of Ukraine: Import and export control: Checks medicines crossing the border for authenticity and compliance.
Detection of smuggling: Ensures that counterfeit products are not imported into Ukraine
Judicial authorities: Handles cases related to violations of legislation in the field of production and distribution of counterfeit goods
Accounting Chamber: Financial control
Verkhovna Rada: Legislative control
Cabinet of Ministers of Ukraine: coordinates the work of the authorities and oversees the implementation of state anti-counterfeiting plans.

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.
Establishing mobile pharmacies and organising their operation. The relevant amendments to the Licensing Conditions were approved by the Government Resolution No. 809 dated 04.08.2023, which entered into force on 09.10.2023.Involved LLCs, State Enterpriseses, Ukrainian Red Cross Societies, Individual enterpreneurs.

The Laws of Ukraine 'On Amendments to Article 19 of the Law of Ukraine *"On Medicinal Products"* regarding the Electronic Retail Trade of Medicinal Products, *"On Licensing of Economic Activities"*.

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.

Substandard and Falsified Medical Products

The State Service of Ukraine on Medicines and Drugs Control participates in the WHO Member State Mechanism on Substandard and Falsified Medical Products.

A contact person from the State Service of Ukraine on Medicines and Drugs Control has been appointed to exchange information, receive and transmit reports on suspicious quality and defects of medicinal products with WHO, EMA and other competent authorities in the field of quality control of medicinal products.

A national coordinator has been appointed to liaise with WHO contact points.

Not solely dedicated to combating counterfeit medical products and similar crimes involving threats to public health.

The State Service of Ukraine on Medicines and Drugs Control is represented in the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO) of the European Directorate for Quality Control of Medical Products and Healthcare (EDQM); in the Committee of Experts on Quality and Safety Standards for Pharmaceutical Practice and Pharmaceutical Care (CD-P-PH/PC) of the European Directorate for Quality Control of Medical Products and Healthcare (EDQM) and participate in the meetings of the European Committee on Cosmetics and Consumer Health (CD-P-COS).

Ukraine, represented by the State Service of Ukraine on Medicines and Drugs Control in the following international organisations:

International Pharmaceutical Inspection Cooperation Scheme (2011) (PIC/S) and the European Commission on Pharmacopoeia.

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.

Citizens and organisations can report suspicious products directly to the State Service of Ukraine on Medicines and Drugs Control via e-mail (dls@dls.gov.ua) or by submitting an electronic request on the official website. The website also provides contact numbers of the responsible persons for the quality of medicinal products.

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.

Contact persons from the State Service of Ukraine on Medicines and Drugs Control were appointed to exchange information within the WHO Global System for Surveillance and Monitoring of Substandard and Falsified Medical Products and a candidate was submitted to

the WHO to appoint as a national coordinator from Ukraine on substandard medicines and medical products within the WHO Member States' Mechanism on Substandard and Falsified Products.

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? Yes. The Order of the Ministry of Health of Ukraine No. 1724 dated 23.09.2022 approved the Procedure for the exchange of information between the Ministry of Health of Ukraine, the State Enterprise "State Expert Center".

Exchange of information and quality control with territorial bodies takes place according to SOP-02-20 of the SMDC of Ukraine '*Urgent actions of the State Service of Ukraine on Medicines and Drugs Control /its territorial bodies/authorised laboratories in case of declaration in circulation of poor-quality/suspected of falsification/imported with violation of the conditions of the current legislation/medicines, during the use of which unforeseen adverse reactions and/or death of a person occurred, or receipt of information on lack of efficacy of medicines'*. Criminal Procedure Code of Ukraine provides mechanisms for cooperation between law enforcement agencies of Ukraine and their international partners. Articles of the Code regulate procedures for international legal assistance, transfer of evidence, and exchange of information.

Law of Ukraine *"On Ratification of the European Convention on Reciprocity to Assist in Criminal Matters, 1959, Additional Protocol of 1978 to the Convention"*

Law of Ukraine *"On Medicinal Products"* provides for the exchange of information between state authorities on the registration, certification and detection of counterfeit medicines. Provides for the exchange of information between state authorities on the registration, certification and detection of counterfeit medicines

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?

The Law of Ukraine *"On Medicinal Products"* establishes the obligation for manufacturers, importers and distributors to report the detection of counterfeit or substandard medicinal products to the State Service of Ukraine on Medicines and Drugs Control. It provides for the

obligation to withdraw such products from circulation and immediately inform the relevant authorities

The Law of Ukraine *"On the Fundamentals of the Legislation of Ukraine on Healthcare"*: Obliges pharmaceutical market players to assist state authorities in identifying and preventing risks related to counterfeiting of medicines.

The Criminal Code of Ukraine: Article 321-1: Criminalises the production, sale and storage of counterfeit medicines.Imposes liability on those who fail to report or conceal facts related to the falsification of products.

The Law of Ukraine *"On Protection of Consumer Rights"*: Obliges to inform consumers and relevant authorities about detection of dangerous products that may cause harm to health or life.

All participants in the pharmaceutical market must immediately notify the State Service of Ukraine on Medicines and Drugs Control of any suspected counterfeit or detected counterfeit products. A letter or an electronic appeal through the official portal of the State Service of Ukraine on Medicines and Drugs Control Use of special notification forms.

Pharmacovigilance system.

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? Yes.

- Articles 13-16, Law of Ukraine *"On Basic Principles of State Supervision (Control) in the Field of Economic Activity"*
- Law of Ukraine *"On State Market Supervision and Control of Non-Food Products"*
- Resolution of the Cabinet of Ministers of Ukraine of 31 October 2007 No. 1280 "*On Approval of the Procedure for Sampling Products to Determine their Quality Indicators and the Form of the Product Sampling Report"*
- Resolution of the Cabinet of Ministers of Ukraine of 14 September No.2005 № 902 *"On Approval of the Procedure for State Quality Control of Medicinal Products Imported into Ukraine"*
- Resolution of the Cabinet of Ministers of Ukraine of 03.02.2010 No. 260 *"Some issues of State Quality Control of medicines" (as amended)"*
- SOP-02-19 *"Procedure for sampling of medicinal products in the implementation of measures of state supervision (control)"*.
- SOP-02-1 *"Procedure for Formation of an Sample List of Medicinal Products to be Sampled in the Course of Planned State Control (Supervision)"*.

The State Service of Ukraine on Medicines and Drugs Control is the central authority responsible for quality and safety control of medicines and medicinal products, as well as for

supervision of falsification of medicines. It develops and implements appropriate measures for sampling, monitoring and detection of falsifications.
The State Service of Ukraine on Medicines and Drugs Control annually forms a Model/Indicative List of Medicines for Selection during Scheduled State Control (Supervision) Activities for the Purpose of Conducting Laboratory Analysis of Medicines for Compliance with Established Requirements for Quality Indicators.
The approximate List of Medicines for Selection during Scheduled State Control (Supervision) includes the nomenclature and frequency of sampling.
The nomenclature and frequency of sampling are determined by the State Service of Ukraine on Medicines and Drugs Control on the basis of a summary of negative results of laboratory tests of samples of a batch or batches of medicinal products received during the previous reporting period, investigations of situations with counterfeit medicinal products, established discrepancies that were classified as class 1, to the order of the Ministry of Health of Ukraine dated 22.11.2011 No. 809 *"On approval of the Procedure for establishing a ban (temporary ban) and resumption of circulation of medicinal products on the territory of Ukraine"*, registered with the Ministry of Justice of Ukraine on 30.01.2012 No. 126/20439 and taking into account complaints from consumers.
When forming the Plan, information received from the Department of Licensing of Production of Medicines, Blood and Certification and the Department of Wholesale and Retail Trade of Medicines is also taken into account based on the analysis of data:

- regarding the prohibition (stoppage) of production of medicines by manufacturers of medicines;
- the results of inspection, suspension and cancellation of Certificates of Conformity of the conditions of production of medicinal products with the GMP requirements and Conclusions on confirmation of conformity of the conditions of production of medicinal products with the GMP requirements. Risk analysis is used when forming the Plan

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? Medicines that meet the legal requirements are allowed for public procurement (as p. 24)
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? *Customs Code of Ukraine*: Empowers customs authorities to detain goods suspected of being counterfeit, including medical products, to prevent their entry into the Ukrainian market.
Customs Code of Ukraine: The Customs Code regulates the activities of the customs authorities, including the procedures for controlling and detaining goods that may violate the

requirements of the law. The State Customs Service of Ukraine has the right to detain goods suspected of infringement, including counterfeit medicines.

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?
The definition of 'medical products' in Ukrainian legislation does not fully correspond to the definition in Article 4.a of the MEDICRIM Convention. The term 'medical products' may cover a broader range of objects, such as medicines, medical devices, auxiliary materials, or a narrower one, such as only medicines used for treatment.

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?
Falsified medicinal product means a medicinal product that is intentionally labelled non-identically (inconsistently) with the information (one or more of them) about the medicinal product with the corresponding name entered in the State Register of Medicinal Products of Ukraine, as well as a medicinal product that is intentionally counterfeited in another way and does not correspond to the information (one or more of them), including the composition, about the medicinal product with the corresponding name entered in the State Register of Medicinal Products of Ukraine.

Thus, the Law of Ukraine *"On Medicines"* defines "falsified medicines" in a limited manner, particularly in this Law, the term 'falsified medicinal product' refers to those medicinal products that have been authorised for circulation on the territory of the country. Consequently, unauthorized medicines are often not classified as falsified, which is inconsistent with the broader definition in the MEDICRIME Convention.

The new Law of Ukraine *"On Medicines"*, that comes into effect in 2027 provides for the introduction of relevant amendments/ In this Law:

Falsified medicinal product - any medicinal product intentionally counterfeited in such a way as to mislead as to its:
- Identity, including packaging, labelling, name, composition, in particular any of its ingredients, including excipients, and the strength of action of these ingredients

- origin, including data on the manufacturer, country of manufacture, country of origin or holder of the registration/trade licence (other authorisation document for the market authorisation of the medicinal product)
- history of circulation, including data and documents on the supply/distribution routes used.

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.

Ukraine has taken significant steps to ensure the criminalisation of offences related to the falsification of medicines and medical devices, as defined in Articles 4.a and 4.j of the Council of Europe Convention. This includes the implementation of relevant provisions in the Criminal Code, strengthening of control, cooperation with international bodies and punishment for violations. All of these measures partially meet the requirements of Articles 5 and 6 of the Convention by facilitating effective investigation and prosecution of counterfeiters.

However, Article 321-1 of the Criminal Code of Ukraine provides for criminal liability for the falsification of medicines, but does not mention medical devices. Accordingly, crimes related to the falsification of medical devices do not fall under this article. In 2020, Article 321-1 was amended to increase liability for the falsification of medicines. These changes, though, don`t cover medical devices.

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.

Ukraine has taken a number of measures to comply with the requirements of the Council of Europe Convention on the criminalisation of offences related to the counterfeiting of medicines, in particular through appropriate amendments to criminal and administrative legislation, as well as through the development of a control system and international cooperation. In order to combat the counterfeiting of medicines and medical devices, Ukraine actively cooperates with international organisations such as the WHO, as well as other states to exchange information, check product quality and investigate international crimes related to counterfeit medical products.

Key steps taken to implement international standards:

1. Criminalisation of counterfeiting of medical products in the Criminal Code of Ukraine. The Criminal Code of Ukraine has been amended to provide for criminal liability for counterfeiting of medicinal products (Article 321 provides for criminal liability for the production, storage, transportation, sale or other distribution of counterfeit medicinal products. Persons involved in counterfeiting of medicinal products are subject to criminal punishment, which may include fines or imprisonment).

Legislative initiatives aimed at combating counterfeiting of medicinal products
- The Law of Ukraine *"On Medicinal Products"* (No. 123/96-BP) was adopted,
- a draft Law of Ukraine "*On Medical Devices"* was developed.

Development of the system of control and supervision over medicinal products and medical devices

Introduction of new technologies for testing medicinal products

To combat counterfeit medicines, Ukraine is actively introducing the latest technologies, such as serial number tracking systems for medicines or special labelling on packaging, which allows for quick verification of product authenticity.

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.

Criminalisation of document forgery in the Criminal Code of Ukraine:

- Article 358 of the Criminal Code of Ukraine ('Forgery of Documents, Seals, Stamps and Forms'): this article criminalises forgery of documents used for certification, registration or circulation of medicines and medical devices. This includes documents confirming the safety and quality of medical products, such as quality certificates, clinical trial reports and other official documents.
- Article 366 of the Criminal Code of Ukraine ('Official forgery'): this article provides for liability for forgery of documents by officials. In particular, if falsified documents related to medicines and medicinal products are created or used by officials, they are subject to criminal liability.
- The Law of Ukraine *"On Medicinal Products"* - regulates the requirements for registration, circulation and control of medicinal products, as well as defines the legal norms regarding the documents required for the introduction of these products to the Ukrainian market.
- The Draft Law of Ukraine *"On Medical Devices"* - although not yet adopted, this law provides for legal provisions to regulate the circulation of medical devices, including registration and certification. This draft law also mentions documents accompanying medical devices that may be counterfeit, such as quality and conformity certificates.

Control over the circulation of medicinal products and medical devices:

- The State Service of Ukraine on Medicines and Drugs Control is responsible for controlling the circulation of medicines and medical devices in Ukraine. Part of this control is the verification of documents accompanying these products for their authenticity. In case of detection of forged documents, the State Service of Ukraine on Medicines and Drugs Control has the right to initiate inspections and apply to law enforcement agencies.

f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)?

The State Service of Ukraine on Medicines and Drugs Control actively informs manufacturers and suppliers about legal requirements, the consequences of violations and liability for falsification of medicines, as well as provides recommendations, conducts inspections and monitors the activities of companies in this area. - Official clarifications and information letters: The State Service of Ukraine on Medicines and Drugs Control, the Ministry of Health and other government institutions regularly publish explanations on the rules of circulation of medicinal products and medical devices. Theese institutions share information on the consequences of violations, including criminal liability for counterfeiting products or non-

compliance with certification requirements. Relevant information is posted on the websites of government agencies responsible for product quality, including medical products.

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: any national specialised investigation units dedicated to:

1) conducting criminal investigations, and/or

State Service of Ukraine on Medicines and Drugs Control (SMDC):
Quality control of medicinal products on the market.Detection and withdrawal of counterfeit medical products from the market.Conducting inspections of pharmaceutical business entities. The State Service initiates investigations in case of detection of counterfeit products and cooperates with law enforcement agencies.

Cyber Police of Ukraine (Cyber Police Department):
Detection of illegal trade in counterfeit medicines via the Internet.
Investigation of cases of advertising and sale of counterfeit medical products on online platforms.Monitoring and closure of illegal online stores and websites.

Security Service of Ukraine (SSU):
Investigating crimes that pose a threat to national security, including the mass supply of counterfeit medical products.Countering transnational criminal groups involved in the manufacture and distribution of counterfeit medicines.
The SSU participated in the exposure of criminal schemes during the COVID-19 pandemic related to counterfeit vaccines and test kits.

The State Enterprise "State Expert Center Ministry of Health of Ukraine":
Monitor side effects of medicines and detect counterfeits through the pharmacovigilance system. Reports from healthcare facilities and patients can trigger investigations.

2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure;

The State Service of Ukraine on Medicines and Drugs Control, the National Police, the Security Service of Ukraine (SSU) are conducting joint activities to detect crimes, including investigations of online sales. Interagency Working Group to Combat Counterfeit Medicines:
Coordinated by the Ministry of Health of Ukraine and includes representatives of law enforcement agencies and industry.

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.

The Prosecutor's Office of Ukraine does not have a separate specialised unit dedicated exclusively to the falsification of medical devices. However, crimes against public health,

including the falsification of medicines, are considered as part of general criminal proceedings. The Prosecutor's Office acts as a supervisory authority over the pre-trial investigation of such crimes conducted by investigators of the National Police or other law enforcement agencies.
In Ukraine, various government agencies are involved in combating the counterfeiting of medical products: National Policy of Ukraine, Security Service of Ukraine

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;

National Police of Ukraine: Investigation of crimes related to the illegal manufacture, distribution or storage of counterfeit medical products.Investigative units at the local level (for general crimes).
The Security Service of Ukraine (SSU): Crimes that have a potential impact on national security, such as large-scale supply of counterfeit medicines through international channels; crimes related to organised groups or foreign suppliers.
The State Service of Ukraine on Medicines and Drugs Control: Dealing with crimes that may cause significant harm to public health. Identification and documentation of violations related to counterfeit medicines, transfer of materials to law enforcement agencies (National Police or the Security Service of Ukraine) for further investigation.
Cyberpolice of Ukraine: Detection of illegal trade in counterfeit medical products on the Internet, closure of websites and online platforms distributing counterfeit products.
The Prosecutor's Office of Ukraine: Supervision of compliance with the law during ongoing investigations.
Distribution of responsibility:
The authority initiating the investigation retains the lead role at the initial stage.
If elements of the crime are found to be beyond its competence (e.g., involvement of international criminal groups), the case may be transferred to another agency, such as the SSU.
In complex cases, interagency meetings are held to coordinate actions.
The State Service of Ukraine on Medicines and Drugs provides investigators with materials on product quality, and the cyber police with information on online sales.

Peculiarities during the COVID-19 pandemic: During the pandemic, all agencies coordinated their actions more closely due to the need to respond quickly to the threat posed by the spread of counterfeit vaccines and test systems. Temporary interagency working groups were established to combat such crimes.

b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3. b). The Security Service of Ukraine is investigating more serious crimes related to the pandemic, such as fraud in the supply of medical supplies or embezzlement. The National Anti-Corruption Bureau of Ukraine is investigating corruption offences related to the misuse of funds.

The State Audit Service checks procurement to identify irregularities. Ukraine cooperates with international organisations such as the WHO to ensure effective monitoring and information exchange in the fight against the pandemic. This also applies to the prevention of illicit trafficking in vaccines and medicines.

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.

Reporting may be done by telephone, email, via an online platform. Each appeal is registered, and the applicant (if the message is not anonymous) has the right to receive information on the progress of the review.

Evaluation of the work of hotlines: State bodyes regularly publish reports on the number of complaints received and their status.

The performance of the systems is assessed through internal audits and statistical analysis. The results of the work can also be viewed in the annual reports of the agencies.

Question 31. **(mandatory)**

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

In most cases, the review process is a combination of an individual approach to each case and systematisation of data at the national level to improve the mechanisms for combating fraud.

Question 32. **(mandatory)**

Are all prescribed offences in Articles 5-8, and Article 9 investigated? Are they subject to a complaint being made and maintained (Article 15)? Yes. Offences in Articles 5-8, and Article 9 are investigated. The investigation does not take place in the following cases:

- No complaint or notification of a violation.
- Insufficient evidence to open proceedings.
- Closure of cases due to lack of prospects of proving guilt.
- Formal approach of certain services (for example, ineffective control or inspections).

Thus, complaints play a key role in the detection and investigation of offences. However, systematic state control measures are also aimed at preventing and detecting such crimes even in the absence of individual complaints.

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)?
Relevant articles of the Criminal Code of Ukraine:

Article 321-1 provides for criminal liability for falsification of medicinal products or trafficking in falsified medicinal products.

Article 305 relates to smuggling of narcotic drugs, psychotropic substances, their analogues or precursors.

Article 321establishes liability for the illegal production, manufacture, acquisition, storage, transportation, shipment or sale of poisonous or potent substances.
Article 326 provides for penalties for violation of sanitary rules and regulations on the prevention of infectious diseases and mass poisoning.

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?
In Ukraine, the investigation of counterfeit medical products is carried out in accordance with the Criminal Procedure Code (CPC) of Ukraine. Pursuant to Article 214 of the CPC, an investigator or prosecutor is obliged to immediately, but not later than 24 hours after receiving a statement or notification of a criminal offence, enter the relevant information into the Unified Register of Pre-trial Investigations (URPI) and initiate an investigation.

The CPC does not require compliance with the jurisdictional rules when entering information into the URPTI. This means that the investigator or prosecutor cannot refuse to enter information into the URPTI on the grounds that the criminal offence is not under their jurisdiction. Thus, the discretionary powers to initiate an investigation without referral to other authorities are limited, and the investigator or prosecutor is obliged to initiate an investigation upon receipt of the relevant information.

With respect to termination of the investigation, the investigator or prosecutor may close the criminal proceedings on the grounds set out in Article 284 of the CPC of Ukraine, in particular, if it is established that no criminal offence has occurred, that the act does not constitute a criminal offence or if there is insufficient evidence to prove the person's guilt in court. Such a decision may be made without recourse to the prosecutor's office or other authorities, but it is subject to appeal in accordance with the provisions of the CPC.

Thus, the procedural rules of Ukrainian law provide for the obligation of the investigator or prosecutor to initiate an investigation into the falsification of medical products upon receipt of relevant information, without discretionary powers in this regard. Termination of the investigation is possible if there are grounds specified by law and may be carried out without

recourse to other authorities, but in compliance with the procedure provided for by the CPC of Ukraine.

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).

All internal procedures of the State Service of Ukraine on Medicines and Drugs Control are designed to meet the requirements of the Legislation:

- Quality Policy of State Service of Ukraine on Medicines and Drugs Control.
- SOP-01 "*Document Management*". Exchange of information and quality control with territorial bodies takes place in accordance with SOP-02-20 of the SMDC of Ukraine 'Urgent actions of the State Service of Ukraine on Medicines and Drugs control in case of declaration of low-quality/suspected of falsification in violation of the current legislation in circulation, in case of unforeseen adverse reactions and/or death of a person, or information on lack of efficacy of medicines'.

Orders of the State Service of Ukraine on Medicines and Drugs Control contain information for territorial bodies of the State State Service of Ukraine on Medicines and Drugs Control, as well as for business entities that sell, store and use medicinal products, immediately after receipt of this Order to check the availability of the specified medicinal product, generalised information on actions and measures to be taken in relation to the prohibited drug, namely: placement in quarantine or take measures to withdraw the specified medicinal product from circulation.

In case of destruction of waste medicinal product within two weeks the information shall be sent to the territorial body of the State Service of Ukraine on Medicines and Drugs Control and a copy of the act on destruction of waste medicinal product shall be provided. Territorial bodies of the State State Service of Ukraine on Medicines and Drugs Control immediately inform all business entities on their territory about the content of the Orders, letters of the State Service of Ukraine on Medicines and Drugs Control on resumption of circulation of the medicinal product.

Coordination and communication with other agencies, groups and other departments/units is also carried out through the following main communication channels: e-mail, EIAS, EDMS 'Megapolis. Document Management', System of e-interaction of Executive Authorities.

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?

Criminal liability for counterfeiting of medicinal products or trafficking in counterfeit medicinal products was introduced in Ukraine in September 2011.

In the criminal substantive law of Ukraine, counterfeit medicinal products are the objects of the following offences:

1) counterfeiting of counterfeit medicinal products (Article 305 of the Criminal Code of Ukraine);

2) counterfeiting of medicinal products or trafficking in counterfeit medicinal products (Article 321-1 of the Criminal Code of Ukraine).

Regarding administrative liability for the falsification of medicinal products, it should be noted that the relevant provision appeared in the Code of Administrative Offences at the end of 2011. Thus, Article 44-2 of the Code established administrative liability for the intentional manufacture, purchase, transportation, shipment or storage with intent to sell or sale of knowingly counterfeit medicines committed in small amounts.

the Law of Ukraine No. 284-IX dated 12 November 2019 "*On Amendments to Article 321-1 of the Criminal Code of Ukraine on Strengthening Liability for Counterfeiting of Medicinal Products or Trafficking in Counterfeit Medicinal Products"*.

The mere fact of committing such an act in the presence of all the elements of a crime (part 1 of Article 3211 of the Criminal Code of Ukraine) already allows for a sentence of imprisonment for a term of 5 to 8 years. In the presence of qualified elements (committed repeatedly or by prior conspiracy by a group of persons, or by an official through abuse of office, a medical or pharmaceutical worker, or through information systems, including the Internet, or in large amounts, or if they caused a long-term health disorder of a person, as well as the production of counterfeit medicines), the penalty is increased to imprisonment for a term of 8 to 10 years with disqualification to hold certain positions or engage in certain activities for up to 3 years and confiscation of property.

In cases where such actions have caused the death of a person or other serious consequences, or have been committed on a particularly large scale, the penalty is imprisonment for a term of 10 to 15 years or life imprisonment with confiscation of property.

For smuggling of counterfeit medicines, the sanctions of parts 1, 2 and 3 of Article 305 of the Criminal Code of Ukraine provide for a penalty of 5 to 12 years' imprisonment with confiscation of property. As we can see, the falsification of medicinal products, as well as trafficking in falsified medicinal products and their smuggling, are subject to very severe liability.

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?

In Ukraine, the prosecution of multiple criminal offenses committed by the same individual is governed by the Criminal Code and the Criminal Procedure Code. When an individual commits multiple offenses, each offense is typically considered independently, and the individual may be held liable for each violation. The concept of "cumulative offenses" is addressed in Article 33 of the Criminal Code of Ukraine, which states: "Committing two or more criminal offenses provided for by different Articles of this Code shall be recognized as repetition only in cases prescribed in the Special Part.

This means that if a person commits multiple offenses, such as trafficking controlled substances and distributing counterfeit medical products, each act is treated as a separate crime. The law does not provide for the subordination of one offense to another; instead, each offense is prosecuted based on its specific elements and the evidence presented.

During a pandemic, while certain offenses related to public health may receive increased attention or carry enhanced penalties, there is no provision in Ukrainian law that subordinates offenses under Articles 5-9 to other criminal offenses. Each offense is adjudicated based on its own merits, and the courts consider the circumstances of each case individually.

Therefore, in the scenario where an individual is prosecuted for both trafficking controlled substances and distributing counterfeit medical products, Ukrainian law mandates that each offense be addressed separately, without one being subordinate to the other.

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?

Yes, in the case of counterfeiting of medical products, offences may be qualified under various articles of the Criminal Code of Ukraine (CCU), in particular:

Counterfeiting of medicines or trafficking in counterfeit medicines Art. 321-1 of the CCU

- Illegal manufacture, purchase, transportation, shipment, storage with intent to sell or sale of counterfeit medicines.
- It provides for severe punishment, including imprisonment for up to 10 years with confiscation of property.

Smuggling of counterfeit medicinal products. 201 of the CCU

- Illegal movement of counterfeit medicines across the customs border of Ukraine.
- The penalty may include imprisonment for a term of 3 to 7 years, and in case of a group conspiracy or in large amounts - up to 12 years with confiscation of property.

Violation of the established procedure for the circulation of narcotic, psychotropic substances and their analogues Article 305 of the Criminal Code (if the counterfeit medicines contain such substances).

Fraud Art. 190 of the CCU
- If the falsification is accompanied by deception of consumers or medical institutions, it may be classified as fraud.

Crimes against life and health of a person -Arts. 119, 121, 122 OF THE CCU
- If the use of counterfeit medicines causes serious bodily harm or death.

Pursuant to Article 67(1) of the Criminal Code of Ukraine, aggravating circumstances include the commission of a crime in a state of emergency or during a military, armed conflict or mass riots, as well as during an epidemic or pandemic.

Thus, if the falsification of medicines or their sale occurred during a pandemic, the court may take this fact into account as an aggravating circumstance and impose a more severe punishment within the sanction of the relevant article of the CCU.

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).

Criminal liability (Articles 321, 321[1]): the falsification of medical devices and medicinal products and abuse of professional powers are punishable by criminal penalties, which may include imprisonment. In addition, the perpetrator of such an offence may be deprived of the right to hold certain positions or engage in certain professions.

The Law of Ukraine *"On Licensing of Economic Activities"* provides for the cancellation of licences for legal entities in case of serious violations of safety standards, such as the production of counterfeit medical devices.

The Law of Ukraine *"On Medicinal Products"* provides for sanctions, including revocation of the licence to sell or manufacture medicinal products, in case of violations related to product falsification.

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.

The State Service of Ukraine on Medicines and Drugs Control (SMDC/Ukraine) inspects medicinal products for compliance with standards and keeps records of detected falsifications through databases and registers. The SMDC/Ukraine receives information from territorial

authorities, business entities, medical institutions, law enforcement agencies, and consumers. Ukraine cooperates with international organisations, such as the WHO, to collect and share data on the falsification of medical devices.

Collecting and analysing data on pandemic-related counterfeiting of medicinal product, in particular in the market of vaccines, COVID-19 tests and protective equipment. The State Service of Ukraine on Medicines and Drugs Control and the Ministry of Health have been actively collecting information on cases of counterfeiting of such products, as well as information on other counterfeiting schemes that have emerged during the pandemic.
Special campaigns were initiated to inform the public and medical institutions about the dangers of counterfeiting COVID-19-related products and the need to carefully check the origin of such goods.

Specify what mechanisms have been established for data collection.

b. Provide the relevant data collected, in particular that during the COVID-19 pandemic, and any reports from the analysis of this data.

The Automated Information System for Pharmacovigilance is a website to support the process of surveillance of adverse reactions or lack of efficacy of medicines in Ukraine. Reporting of adverse reactions and/or lack of efficacy of a medicinal product, vaccine, tuberculin and adverse event after immunization.

Public Health Center (PHC) Dashboard: The PHC developed an interactive dashboard that provided daily updates on laboratory-confirmed COVID-19 cases, recoveries, and fatalities. This tool offered detailed statistics by region, gender and age group, facilitating comprehensive monitoring of the pandemic's progression.

First Few Cases Study: In June 2020, the World Health Organization (WHO), in collaboration with the Ministry of Health of Ukraine and the Ukrainian Public Health Center, initiated the "First Few Cases" study across 11 regions. This study aimed to collect detailed data on initial COVID-19 cases and their contacts to understand transmission dynamics and inform response strategies.

c. 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.
In total, over the years of its existence from 2017 to 2020, the AISF received more than 114 thousand reports of adverse events and adverse events after immunization. These data collection mechanisms provided critical insights into the pandemic's trajectory in Ukraine, informing public health decisions and response strategies.