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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 2nd thematic monitoring round:

Deposit and destruction measure of seized counterfeit[1] medical products, active substances, excipients, parts, materials, and accessories

As adopted by the MEDICRIME Committee on the 22nd November 2024

Replies should be addressed to the MEDICRIME Committee Secretariat

medicrime@coe.int

Phase 1: by 30 May 2025
Phase 2: by 28 November 2025
Phase 3: by 29 May 2026

[1] Guidance Note to meaning of counterfeit being the same as falsified.

Please specify who made the submission to the questionnaire on behalf of the country.

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Please specify which state bodies/authorities (and, at the discretion of the country, where relevant, civil society and external contributors) contributed to responding to this questionnaire.

Name of state bodies/authorities contributing to responding to the questionnaire	State Service of Ukraine on Medicines and Drugs Control National Policy of Ukraine Central Laboratory for Quality Control of Medicines and Medical Products
Name of civil society contributing to the responding to the questionnaire	
Name of other external contributors to the responding to the questionnaire	

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 detained, seized, and confiscated counterfeit and other illicit medical products have the potential to be returned illegally to the marketplace, whether to the illicit market or infiltrated into the legitimate supply chain of medical products, the MEDICRIME Committee decided that the second monitoring round would focus on the "Deposit and destruction measure of seized counterfeit medical products, active substances, excipients, parts, materials, and accessories".[2]

4. On 22 November 2024, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to the handling and final disposal of detained, seized and confiscated medical products and similar crimes involving threats to public health. 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"), the 1st thematic monitoring round (in particular at question 4), 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 to the questionnaires shall be detailed, as comprehensive as possible, answer all*

[2] Committee of the Parties of the MEDICRIME Convention, *List of decisions*, 7th Plenary Meeting (28-29 November 2023), T-MEDICRIME – (2023) LD, paragraph 4.2.

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. The questions in this questionnaire are grouped around Article 12, paragraph 3 of the MEDICRIME Convention concerning issues of seizure, confiscation, and destruction, and to prevent future offending.

7. This thematic questionnaire does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. Article 12, paragraphs 1, and 2 are aimed at providing for the punishment of offenders by effective, proportionate, and dissuasive sanctions, including the seizure and confiscation of the instrumentalities used and the proceeds of crime. This questionnaire focuses more narrowly on the destruction of medical products and instrumentalities used in the commission of the offences. The questionnaire focuses only on specific legislative and other measures taken or envisaged in the context of seizure, confiscation, and destruction to prevent future offending and protect public health.

8. Responses to this thematic questionnaire will be understood against the background information submitted by Parties in reply to the CPQ and the 1st thematic monitoring round (in particular at question 4). Whenever warranted, Parties are invited to refer to such information. Where questions overlap between the CPQ, the 1st monitoring round, 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. If there are differences with the information provided in response to the CPQ and the 1st monitoring round, Parties are kindly requested to specify which State bodies/agencies and, where relevant, NGOs, contributed to responding to this questionnaire.[3]

10. For this questionnaire, the notion of the term "confiscation", which is not defined in the MEDICRIME Convention, can be understood in the context of the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime. Article 1 of

[3] Add relevant authorities who contributed to response, but it is a single country response.

that Convention provides the meaning of "confiscation" to mean a penalty or measure, ordered by a court following proceedings in relation to a criminal offence or criminal offences, resulting in final deprivation of property.

11. For this questionnaire where "**products"** are mentioned, this is taken to refer to those defined in the MEDICRIME Convention as medical products in article 4.a; active substance in article 4.c; excipient in article 4.d; accessory in article 4.f; and parts and materials in article 4. g.

12. For this questionnaire, where "**officials**" are mentioned, this is to be taken to refer to the relevant law enforcement, customs/border agency, regulatory authority, or other person whose duty it is to handle, secure, store or transport, the products mentioned in paragraph 11, above, relating to detentions, seizures and confiscations.

13. Parties are kindly requested to specify in answering the question whether the measure is criminal law, administrative law, and/or whichever other measure.

14. **Parties are kindly requested to refer to the Explanatory Note for specific guidance on what is required in the response to a question.**

15. 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.

Chapter II – Substantive criminal law

Article 12 – Sanctions and measures

3. Each Party shall take the necessary legislative and other measures to:

a. permit seizure and confiscation of:

i. medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;

ii. proceeds of these offences, or property whose value corresponds to such proceeds;

b. permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;

c. take any other appropriate measures in response to an offence, in order to prevent future offences.

Explanatory report

Chapter II – Substantive criminal law

87. Paragraph 3 requires Parties to ensure that measures concerning seizure and confiscation of certain documents, goods and the proceeds derived from offences can be taken. This paragraph has to be read in the light of the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (ETS No. 141) as well as the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime and on the Financing of Terrorism (CETS No. 198), which are based on the idea that confiscating the proceeds of crime is an effective anti-crime weapon.
As all of the offences related to the counterfeiting of medical products and similar crimes are undertaken for financial profit, measures depriving offenders of assets linked to or resulting from the offence are clearly needed in this field as well.

88. Paragraph 3 a, provides for the seizure and confiscation of medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with the Convention or to facilitate their commission. Moreover, proceeds of the offences, or property whose value corresponds to such proceeds may be seized or confiscated.

89. The Convention does not contain definitions of the terms “confiscation”, “instrumentalities”, “proceeds” and “property”. However, Article 1 of the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime provides definitions for these terms which may be used for the purposes of this Convention. By “confiscation” is meant a penalty or measure, ordered by a court following proceedings in relation to a criminal offence or criminal offences, resulting in final deprivation of property.

“Instrumentalities” covers the whole range of things which may be used, or intended for use, in any manner, wholly or in part, to commit the criminal offences. “Proceeds” means any economic advantage or financial saving from a criminal offence. It may consist of any “property” (see the interpretation of that term below). The wording of the paragraph takes into account that there may be differences of national law as regards the type of property which can be confiscated after an offence. It can be possible to confiscate items which are (direct) proceeds of the offence or other property of the offender which, though not directly acquired through the offence, is equivalent in value to its direct proceeds (“substitute assets”). “Property” must therefore be interpreted, in this context, as any property, corporeal or incorporeal, movable or immovable, and legal documents or instruments evidencing title to or interest in such property.

Phase 1

Safe and secure handling

This section aims to collect information on legislation, policies, strategies, plans and other measures designed to ensure the secure and safe collection, handling, storage, and transportation of detained, seized and confiscated counterfeit and other illicitly trafficked medical products from their first point of contact to their final disposal.

Question 1.

QUESTION	YES	NO	Provide details in brief
Do you have any rules, policies, strategies or other measures in place that are designed to ensure the **safe handling by officials** of:			
• Detained medical products (medicinal products and medical devices (Art 4.a)	YES		**For all items in questions 1 and 2 (except medical devices)** Regulation of the Cabinet of Ministers of Ukraine dated 30.11.2016 *On Approval of the Licensing Conditions* Art.57.The Licensee shall ensure the orderly storage of various categories of materials and products in the warehouse areas: raw materials, packaging materials, intermediate, bulk and finished products, as well as quarantined, authorised for release, rejected, returned or withdrawn medicinal products. Art.62. Raw materials, incoming materials and finished products after their receipt or completion of production before the authorized person issues a permit for use in production or release (sale) shall be kept in quarantine by storing products in separate

			areas or appropriate organizational measures under the conditions established by regulatory and technical documentation. If quarantine is ensured only by storing products in separate areas, such areas must be clearly marked. Access to such areas is allowed only to authorised personnel. Any system used instead of physical quarantine must provide equivalent security. Art.79. Any actions carried out with substances, materials and medicinal products, such as receipt, quarantine, sampling, storage, labelling, manufacturing, distribution, processing, packaging, shall be carried out in accordance with the methods or instructions established by the licensee and shall be recorded. Art.128. The licensee shall withdraw from sale, identify and place in clearly defined and labelled places (quarantine zones) the following medicinal products substandard medicinal products, in particular those that have expired; those prohibited for sale in accordance with the procedure established by law; medicinal products with damaged closures or packaging; medicinal products suspected of being of poor quality and/or falsified; returned medicinal products; falsified medicinal

			products, unregistered medicinal products that are subject to registration. **For all items in questions 1 and 2 concerning medical devices** Law of Ukraine On general safety of non-food products Art. 12. Restrictive (corrective) measures to ensure product safety 1. If the state market surveillance authority has established that products may pose risks under certain conditions, it shall immediately decide whether the manufacturer and/or distributor shall warn consumers (users) of such risks or take measures to bring the products into compliance with the requirements for ensuring product safety before placing them on the Ukrainian market. 2. If the state market surveillance authority has established that products may pose risks to certain categories of consumers (users), it shall immediately decide to warn the relevant consumers (users) of such risks by the manufacturer and/or distributor. 3. If the state market surveillance authority has established that a product may be dangerous under reasonable assumptions, it shall immediately decide on a temporary ban on the introduction

			of such products on the market, including the supply of such products, offering them for supply or demonstration, for the period necessary to conduct the relevant examination (testing).
• Detained active substances (Art 4.c)	YES		
• Detained excipients (Art 4.d)	YES		
• Detained accessories (Art. 4.f)	YES		
• Detained “parts” and “materials” (Art. 4.g)	YES		
• Seized medical products (Art 4.a)	YES		
• Seized active substances (Art 4.c)	YES		
• Seized excipients (Art 4.d)	YES		
• Seized accessories (Art. 4.f)			
• Seized “parts” and “materials” (Art. 4.g)			
• confiscated of medical products (Art 4.a)	YES		
• confiscated active substances (Art 4.c)	YES		
• Confiscated excipients (Art 4.d)	YES		
• Confiscated accessories (Art. 4.f)			
• Confiscated “parts” and “materials” (Art. 4.g)			

Where there is no difference in the treatment of the medical products, active substances, excipients, accessories to a medical device, or parts and materials constructed and designated to be used for medical devices, then brief details provided in the response may be a general consideration applicable to all relevant products.

Question 2

QUESTION	YES	NO	Provide details in brief
Are there rules, processes or other measures governing the **secure and safe collection, and storage** of detained, seized and confiscated products between the point of detention/seizure and the confiscation/forfeiture orders by a court or other permissible procedure for disposal?			
• Detained medical products (medicinal products and medical devices (Art 4.a)	YES		All as in the Question 1
• Detained active substances (Art 4.c)	YES		
• Detained excipients (Art 4.d)	YES		
• Detained accessories (Art. 4.f)			
• Detained "parts" and "materials" (Art. 4.g)			
• Seized medical products (Art 4.a)	YES		
• Seized active substances (Art 4.c)	YES		
• Seized excipients (Art 4.d)	YES		
• Seized accessories (Art. 4.f)			
• Seized "parts" and "materials" (Art. 4.g)			
• confiscated of medical products (Art 4.a)	YES		
• confiscated active substances (Art 4.c)	YES		
• Confiscated excipients (Art 4.d)	YES		
• Confiscated accessories (Art. 4.f)			
• Confiscated "parts" and "materials" (Art. 4.g)			

Question 3

QUESTION	YES	NO	Provide details in brief
Are there rules, processes or other permissible procedures:			
• permitting final disposal without the consent of the owner where there is no court-ordered confiscation?	YES		**Concerning medicinal products (except medical devices)** Order of the Ministry of Health of Ukraine dated 22.11.20111 No 809 *On approval of the Procedure for establishing a prohibition (temporary prohibition) and resumption of circulation of medicinal products in Ukraine* Art.4.5. A business entity that has a batch or

			batches of a medicinal product that are prohibited for circulation, in accordance with the order to establish a ban on circulation, shall send to the territorial bodies of the State Service on Medicines and Drugs Control a notification of the measures taken to implement such an order, together with copies of documents confirming the fact of destruction, disposal or return of the medicinal product to the supplier (manufacturer). **Concerning medical devices** Law of Ukraine On general safety of non-food products Art.4. If the state market surveillance authority has established that the products are dangerous, it shall immediately: **1**) prohibit the introduction of such products on the market and take measures to ensure such prohibition; 2) take measures to immediately withdraw it from circulation and warn consumers (users) of the risks posed by such products; 3) jointly with manufacturers and distributors of such products that have already been provided to consumers (users) on the Ukrainian market, take measures to withdraw them from circulation and destroy them. The recall of products is applied as

			an exceptional measure if the measures taken by the manufacturer or distributor are insufficient to prevent or avoid the relevant risks posed by the products. 5. Restrictive (corrective) measures to ensure the safety of products specified in parts one to four of this Article shall be taken by the state market surveillance authorities in proportion to the level of threat of the relevant products to the public interest. The state market surveillance authorities shall take measures to establish cooperation with producers and distributors in order to prevent or reduce the risks posed by the products offered by them on the market.
• permitting final disposal only with the consent of the owner or with a court confiscation order	YES		**Concerning medical products and medical devices** Customs Code of Ukraine Art 243 Goods and vehicles referred to in clause 3 of Article 461 of this Code confiscated by a court decision shall be sold, and in cases provided for by law, transferred for free possession and use or recycled, disposed of or destroyed within the time limits established by law for the execution of court decisions. Resolution of the Cabinet of Ministers of Ukraine dated 26.12.2001 No 1724

			"On the Procedure for Accounting, Storage, Valuation of Seized Property seized by the customs in respect of which a court decision on confiscation, transfer of this property to the bodies of the State Executive Service and its disposal Art. 2 Accounting, preliminary assessment, as well as responsibility for storage of property seized by customs until a court decision is made on its confiscation are the responsibility of these authorities. Art. 11 Destruction, utilisation or industrial processing of property shall be carried out according to the preliminary assessment made by the customs in accordance with The Procedure for Disposal of Property Confiscated by Court Decision and transferred to the state executive service Resolution of the Cabinet of Ministers of Ukraine dated on 11.07.2002 No 985 "On Approval of the Procedure for Disposal of Property Confiscated by Court Decision and transferred to the state executive service" Art. 18 The decision to destroy the relevant confiscated property shall be taken by the commission. When the commission decides on the destruction of the relevant confiscated property,

			the commission meeting may be attended by a representative of a business entity licensed to production of the relevant category of products (by agreement), a representative of the association of producers and/or importers of the relevant category of products (upon agreement) and a representative of the of the business entity whose trademarks for goods and services the relevant confiscated products are marked with.
• Concerning security and storage where no final disposal consent is provided and the products cannot be returned to the presumed owner?	YES		**Concerning medical products and medical devices** Resolution of the Cabinet of Ministers of Ukraine dated 25 August 1998 No. 1340 "On the Procedure for Accounting, Storage, Evaluation of Confiscated and Other Property Passing into State Ownership and Disposal thereof" Resolution of the Cabinet of Ministers of Ukraine dated on 11.07.2002 No 985 "On Approval of the Procedure for Disposal of Property Confiscated by Court Decision and transferred to the state executive service" Art. 19 Confiscated low-quality products that are unsuitable for recycling is subject to destruction (disposal). Until the issue of on further processing, destruction (disposal),

			substandard and hazardous products may be transferred for temporary storage to storage facilities approved by specially authorized bodies.

Phase 2

Sampling

This section aims to ascertain if the Parties have sampling procedures that guide the selection of detained/seized/confiscated medical products to be handed over for test, examination and analysis and how any residue of the samples is disposed of.

Whether all or only a proportion of them are required to be handed over for analysis, examination or testing, and whether there is a requirement criteria the Parties deploy to select the sampling strategy for analysis, test, or examination

Question 4

QUESTION	YES	NO	Provide details in brief
Are there sampling requirements, rules, or procedures relating to the selection of samples of products that are the subject of an offence established under the MEDICRIME Convention for test, examination and analysis relating to:			
• the contemplation of criminal proceedings	YES		Article 245 of the Criminal Procedure Code of Ukraine (CPC) Parts 1 and 2. 1. If samples are needed for expertise examination, such samples shall be taken by the party to criminal proceedings, which requested expert examination or on whose motion the examination was assigned by the investigating judge. Where an expert examination is commissioned by the court, the taking of samples for same shall be carried out by the court or, on its request, by a specialist involved for this purpose. 2. The way in which samples of objects and documents are taken shall be established in accordance with provisions governing provisional access to objects and documents

• where no criminal proceedings are anticipated to take place and the product is not being returned to the owner	YES		Criminal Procedure Code of Ukraine (CPC): If an investigation or inspection is being conducted, the investigator or prosecutor may initiate the collection of samples even without opening criminal proceedings. Article 237 of the Code of Criminal Procedure — 'Seizure of samples for expert examination' Order of the Ministry of Health of Ukraine dated 27 December 2006 No. 677 'On Approval of the Procedure for State Control of the Quality of Medicinal Products in Ukraine' Paragraph 3, clause 7) "In case of doubt about the quality of medicinal products during visual inspection, the authorised person shall take samples of suspicious medicinal products and send them to the territorial body of the Central Executive Authority that implements state policy in the sphere of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and the circulation of narcotic drugs, psychotropic substances and precursors, counteracting their illegal circulation, for laboratory testing of the quality of medicinal products.

			During such investigations, until a final decision is made on their quality, the batches of suspicious medicinal products shall be kept in a specially designated, clearly defined, marked quarantine zone (room), separate from other products, marked 'Quarantine' with an indication of the reasons for withdrawal from circulation and the date of the movement.

Disposal

This section aims at identifying what specific legislative and other measures exist or are planned to ensure the protection of the environment and the public from the risk of harm from the disposal of evidential and waste medical products following a criminal investigation that is the subject of an offence established under the MEDICRIME Convention or where no prosecution has been initiated

Question 5

QUESTION	YES	NO	Provide details in brief
Are there rules or procedures relating to detained or seized products mentioned in this questionnaire that are the subject of an offence established under the MEDICRIME Convention relating to the disposal by the laboratory of unused samples:			
• destruction by the laboratory of unused samples	YES		Destruction of unused samples by the laboratory is carried out in accordance with the requirements of the laboratory's quality management system documents (SOPs)
• return to the authority/service that provided the samples to the laboratory	YES		Unused samples shall be returned to the authority/service that provided the samples to the Laboratory in cases where this is stipulated by the requirements of

			the authority/service

Question 6

6 a.

QUESTION	YES	NO	Provide details in brief
This question concerns the existence of rules or procedures to ensure the **safe and orderly disposal** following a decision that the detained, seized, and confiscated products are no longer required to be retained by the authority/service			
• Are there rules or procedures governing the safe and orderly disposal following a decision that the detained, seized, and confiscated products are no longer required to be retained by the authority/service	YES		Law of Ukraine 'On Medicinal Products' Article 23 Disposal and destruction of medicinal products: Substandard medicinal products, including those that have expired, must be disposed of and destroyed. Order of the Ministry of Health dated 24 April 2015 No. 242 'On Approval of the Rules for Disposal and Destruction of Medicinal Products'. Art. 5 'Medicinal Pruducts that are not subject to further use shall acquire the status of "waste" and shall be transferred for disposal or neutralisation to business entities that have the appropriate licences to conduct economic activities in the field of hazardous waste management, either directly or through suppliers, if this is provided for by the relevant contractual terms.'
• Do the rules or procedures apply where the products are disposed of by incineration or landfill dumping by the authority/service	YES		Law of Ukraine 'On Waste' Article 5. Animal by-products not intended for human consumption, the circulation of which is regulated by the Law of Ukraine 'On animal

			by-products not intended for human consumption', except for those that are incinerated, buried or used for biogas and compost. Illegal burial or burning of waste is prohibited. Disposal is carried out exclusively at licensed enterprises, taking into account the hazard class of the waste. Section VI. Incineration, co-incineration and landfilling of waste Article 40. General requirements for waste disposal. 1. Waste disposal shall be carried out at landfills that comply with the requirements of the law and whose technological equipment ensures the protection of groundwater, the removal and neutralisation of biogas and leachate, and the control of emissions into the atmosphere and contamination of soil and groundwater. The entity managing the landfill site must have a permit to carry out waste treatment operations and, in the case of hazardous waste disposal, a licence to carry out economic activities involving the management of hazardous waste. Resolution of the Cabinet of Ministers of Ukraine dated 13 July 2000 No. 442 'On Approval of the

			Procedure for Disposal and Destruction of Substandard Medicinal Products' Establishes the disposal procedure: drawing up a disposal report, transferring the medicines to a licensed organization, using methods such as incineration or burial in special landfills. Order of the Ministry of Health of Ukraine dated 24 April 2015 No. 242 'On Approval of the Rules for the Disposal and Destruction of Medicinal Products' defines the requirements for the destruction and disposal of substandard, counterfeit and unregistered medicinal products, including those which are expired
• Do the rules or procedures apply where the disposal is contracted out to an authorized/licensed environmental disposal contractor	YES		Law of Ukraine 'On Medicinal Products' — general rule (Article 23). Law of Ukraine 'On Waste Management' — obligation to conclude contracts with licensed operators (Article 32). Order of the Ministry of Health dated 24 April 2015 No. 242 'On Approval of the Rules for the Disposal and Destruction of Medicinal Products'— details the procedure and directly mentions the contractual terms of transfer (clause 3.4). Resolution of the Cabinet of Ministers of

			Ukraine dated 13 July 2016 No. 446 defines the requirements for such contractors (licensing conditions)

6 bis

QUESTION	YES	NO	Provide details in brief
This question concerns the existence of **safe and orderly disposal** following a decision that the detained, seized, and confiscated products, including Article 8.a related products, are no longer required to be retained by the authority/service			
• Is donation permitted for use or consumption by the domestic authorities or for providing to third countries?	YES		Order of the Ministry of Health of Ukraine dated 24 April 2015 No. 242'On Approval of the Rules for Disposal and Destruction of Medicinal products'. stipulates that medicinal products that are not subject to use have the status of waste and may only be transferred to entities that have a license to handle hazardous waste. Transfer in the form of donations or humanitarian aid is not permitted
• Is the donation permitted to institutions for the purpose of training and research?	YES		Order of the Ministry of Health of Ukraine dated 24 April 2015 No. 242 'On Approval of the Rules for the Disposal and Destruction of Medicines' Unsuitable/poor-quality medicines are considered waste. The transfer of such medicines, even for training or research purposes, is not permitted

• Is repurposing permitted as a means of disposal, including by putting back into the supply chain or for use in medical establishments and clinics, of instrumentalities involved in the offence, or donation, including to research institutions, If so, please provide brief details?	YES		Order of the Ministry of Health of Ukraine dated 24 April 2015 No. 242 'On Approval of the Rules for the Disposal and Destruction of Medicinal Products' It is not permitted to repurpose, as a means of disposal, including by returning to the supply chain or for use in medical institutions and clinics, instruments of crime, or donations, including to research institutions

Question 7

QUESTION	YES	NO	Provide details in brief
This question concerns any monitoring undertaken of health and environmental risk or impacts arising from the handling, storage, and disposal of detained, seized or confiscated medical products.			
• Is there monitoring based on scientific studies or other similar reports	YES		Law of Ukraine 'On Waste Management' — control of impact on the environment and health Resolution of the Cabinet of Ministers of Ukraine No. 121 dated 08.02.2022 'On Approval of the Procedure for Monitoring and Control in the Sphere of Waste Management'. Order of the Ministry of Health of Ukraine dated 31.10.2025 No. 1827 'On Approval of State Sanitary Norms and Rules 'Procedure for Medical Waste Management, Including Requirements for Human Health Safety during the Generation, Collection, Storage, Transportation, and Treatment of Such Waste' Requirements for Risk Assessment by Waste Category.'
• Is there monitoring based on reports of injuries or environmental damage done	YES		Law of Ukraine 'On Environmental Protection' Section V Observation, Forecasting, Accounting and Reporting in the Field of Environmental Protection Article 22. Monitoring of the Environment Resolution of the Cabinet of Ministers of Ukraine No. 121 dated

			08.02.2022 'On Approval of the Procedure for Monitoring and Control in the Field of Waste Management'. Monitoring of risks to human health and the environment posed by seized/confiscated medicinal products and medical devices is carried out reactively, based on reports of harm, and proactively, through scheduled inspections and monitoring of storage/disposal conditions.

Phase 3 – Training and Auditing

Training

This section aims to ascertain whether there are any **training programmes** in place for those involved in the detention, seizure and confiscation of medical products that are the subject of an offence established under the MEDICRIME Convention to their final disposal to ensure safe handling at all stages and to prevent the recycling and return of such products to the market

Question 8

QUESTION	YES	NO	Provide details in brief
• Are there training programmes for all those involved with handling of detained, seized, and forfeited medical products to ensure their safe handling to protect the handlers and others who may come into contact with those medical products?	YES		*it's fragmented* Employees of the State Service of Ukraine on Medicines and Drugs Control participate in meetings of the Committee of Experts on Minimising Risks to Public Health Caused by Counterfeit Medical Products and Similar Crimes (CD-P-PH/CMED) Training by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and the British Standards Institution (BSI) on: "New requirements of Regulation (EU) 2019/1020".

Question 9

QUESTION	YES	NO	Provide details in brief

• Are there training programmes for all those involved with handling medical products that are the subject of an offence established under the MEDICRIME Convention to prevent the recycling of those medical products and their return to the market		No	
• Do the training programmes include the prevention of instrumentalities used in the counterfeiting of medical products from being recycled and returned to the market		No	

Auditing

This section aims to identify good practices in any review procedures in place that ensure that measures are effective in protecting handlers, the environment and the public from the risk of harm from detained, seized, and confiscated medical products that are subject to an offence established under the MEDICRIME Convention

Question 10

QUESTION	YES	NO	Provide details in brief
This question concerns the existence of audits, reviews, or other oversight programmes and their frequency to understand the effectiveness of measures identified in the 2nd monitoring round relating to medical products, active substances, excipients, accessories, parts and materials that are subject to an offence established under the MEDICRIME Convention.			
• Are there procedures and checks on their effectiveness related to records for detention, seizure and confiscation, secure storage, transportation, dispatch for analysis, and final disposal of such products?	YES		Law of Ukraine 'On the Basic Principles of State Supervision (Control) in the Sphere of Economic Activity' Resolution of the Cabinet of Ministers of Ukraine No. 929 dated 30 November 2016 'On Approval of Licensing Conditions for Economic Activities in the Production of Medicinal Products, Wholesale and Retail Trade in Medicinal Products' Resolution of the Cabinet of Ministers of Ukraine No. 929 dated 30 November 2016 "On Approval of Licensing Conditions for Economic Activities in the Production of Medicinal Products, Wholesale and Retail Trade in Medicinal Products, Wholesale and Retail Trade in Medicinal Products, Import of Medicinal

			Products (except for active pharmaceutical ingredients) Order of the State Service of Ukraine on Medicines and Drugs Control dated 29 November 2024 No. 1780. The Annual Plan for State Supervision (Control) Measures for 2025 has been approved. Order of the Ministry of Health dated 26 October 2001 No. 428 'On Approval of Instructions for Preparing Materials on Administrative Offences under Ukrainian Legislation on Ensuring the Quality of Medicinal Products' Scheduled inspections of business entities include: Quality control of medicinal products; inspections of compliance with requirements in the field of plant cultivation, development, production, manufacture, storage, transportation, purchase, sale (dispensing), import/export to/from the territory of Ukraine, use, destruction of narcotic drugs, psychotropic substances and precursors, approved by Resolution of the Cabinet of Ministers of Ukraine No. 282 dated 06.04.2016. Order of the State Service of Ukraine on

			Medicines and Drugs Control dated 29 November 2024 No. 1780. The Annual Plan for State Supervision (Control) Measures for 2025 has been approved. Order of the Ministry of Health dated 26 October 2001 No. 428 'On Approval of Instructions for Preparing Materials on Administrative Offences under Ukrainian Legislation on Ensuring the Quality of Medicinal Products' Business entities engaged in the sale, storage, and use of medicinal products shall, immediately upon receipt of this order, check the availability of the specified medicinal products, take measures to remove them from circulation by returning them to the supplier/manufacturer or destroying them, and notify the territorial body of the State Service of Ukraine on Medicines and Drugs Control thereof. In the event of destruction of waste products, a copy of the act of destruction of waste medicinal products shall be sent to the territorial body of the State Service of Ukraine on Medicines and Drugs Control within two weeks. Control over the implementation of this order shall be exercised by the territorial bodies of the State Service of

			Ukraine on Medicines and Drugs Control in the relevant territory. Failure to comply with this order shall entail liability in accordance with the current legislation of Ukraine. Control over the implementation of the orders shall be exercised by the territorial bodies of the State Service of Ukraine on Medicines and Drugs Control in the relevant territory. Failure to comply with this order shall entail liability in accordance with the current legislation of Ukraine.
• Are there measures in place and checks on their effectiveness for the personal safety of officials coming into contact with such products	YES		Order of the Ministry of Health of Ukraine dated 31.10.2025 No. 1827 'On Approval of State Sanitary Norms and Rules 'Procedure for Medical Waste Management, Including Requirements for Human Health Safety during the Generation, Collection, Storage, Transportation, and Treatment of Such Waste' Requirements for Risk Assessment by Waste Category.'
• Are there measures in place and checks on their effectiveness relating to the protection of the public resulting from the detention, seizure, and confiscation of such products through to their final disposal?	YES		Order of the Ministry of Health of Ukraine dated 31.10.2025No. 1827 'On Approval of State Sanitary Norms and Rules 'Procedure for Medical Waste Management, Including Requirements for Human Health Safety during the Generation, Collection, Storage, Transportation, and

			Treatment of Such Waste‘ Requirements for Risk Assessment by Waste Category.’
• Are there measures in place and audits conducted on their effectiveness ensuring that where product disposal is contracted out to private or commercial disposal contractors such contractors are: • Permitted by law to conduct disposal in the manner in which disposal is intended for such medical products	YES		Order of the Ministry of Health of Ukraine dated 31.10.2025 No. 1827 ‘On Approval of State Sanitary Norms and Rules ’Procedure for Medical Waste Management, Including Requirements for Human Health Safety during the Generation, Collection, Storage, Transportation, and Treatment of Such Waste‘ Requirements for Risk Assessment by Waste Category.’