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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.

NAME OF THE COUNTRY	TÜRKİYE

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	Ministry of Health Turkish Medicines and Medical Devices Agency
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)	X		Pursuant to the Articles 8 and 9 of the Regulation on Criminal Property, the procedures for the preservation and transfer of criminal property are carried out. In particular, if the criminal property is excessive in number or size or if its transportation requires great costs due to its nature or if it is certain that the criminal property will be damaged during its transportation, it is not sent and kept in its original location.
• Detained active substances (Art 4.c)	X		
• Detained excipients (Art 4.d)	X		
• Detained accessories (Art. 4.f)	X		
• Detained “parts” and “materials” (Art. 4.g)	X		
	X		
• Seized medical products (Art 4.a)	X		
• Seized active substances (Art 4.c)	X		
• Seized excipients (Art 4.d)	X		
• Seized accessories (Art. 4.f)	X		
• Seized “parts” and “materials” (Art. 4.g)	X		
	X		
• confiscated of medical products (Art 4.a)	X		
• confiscated active substances (Art 4.c)	X		
• Confiscated excipients (Art 4.d)	X		
• Confiscated accessories (Art. 4.f)	X		
• Confiscated “parts” and “materials” (Art. 4.g)	X		

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)	X		According to the third paragraph of the Article 10 of the Regulation on Criminal Property, regarding the properties which cannot be kept in the depository office during the investigation and prosecution phases, due to the reason that they might be corrupt or might definitely lose their value, or it is difficult to preserve them due to their nature, number and size; where there is no special relevant regulation, during the investigation phase the judge in charge will be asked, and during the prosecution phase the court handling the case will be asked to render a decision, regarding those above-mentioned properties, to sell them without awaiting the end of investigation or prosecution or to submit them to one of the authorities mentioned in the Article 18 or to another appropriate authority. In addition, in the Article 132 of the Criminal Procedure Code No. 5271, there is a provision on the preservation and disposal of the seized property.
• Detained active substances (Art 4.c)	X		
• Detained excipients (Art 4.d)	X		
• Detained accessories (Art. 4.f)	X		
• Detained “parts” and “materials” (Art. 4.g)	X		
	X		
• Seized medical products (Art 4.a)	X		
• Seized active substances (Art 4.c)	X		
• Seized excipients (Art 4.d)	X		
• Seized accessories (Art. 4.f)	X		
• Seized “parts” and “materials” (Art. 4.g)	X		
	X		
• confiscated of medical products (Art 4.a)	X		
• confiscated active substances (Art 4.c)	X		
• Confiscated excipients (Art 4.d)	X		
• Confiscated accessories (Art. 4.f)	X		
• Confiscated “parts” and “materials” (Art. 4.g)	X		

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?		X	In the fifth paragraph of the Article 11 of the Anti-Smuggling Law No. 5607, there is a provision on the disposal of medicines, pharmaceutical raw materials, products containing pharmaceutical raw materials, medical devices and materials. Provincial Directorates of Health contact the relevant authorities regarding the products, included in the court file or the investigation of the public prosecutor's office, according to the results of the judicial processes; and the disposal process is carried out by obtaining the necessary approvals for the disposal of the products in order to ensure public health.
• permitting final disposal only with the consent of the owner or with a court confiscation order	X		
• Concerning security and storage where no final disposal consent is provided and the products cannot be returned to the presumed owner?	X		

Answer to question 1- 2 and 3:
There is no separate regulation within our Agency in this context, and it is thought that it would be more appropriate to obtain information on the subject from the Ministry of Trade, the Ministry of Internal Affairs and the Ministry of Justice. Methods and legislation used regarding the destruction processes of medicines;
- Article 54 of the Customs Law No. 4458
- Article 19 of the Pharmaceutical and Medical Preparations Law No. 1262
- First paragraph of Article 11 of the Anti-Smuggling Law No. 5607
- Temporary Article 3 of the Anti-Smuggling Law No. 5607
- First paragraph of Article 13 of the Anti-Smuggling Law No. 5607

The process is carried out within the framework of court decisions or opinions from the Agency's Legal Consultancy, and disposal is carried out by authorized/licensed environmental disposal companies in line with the relevant court decisions and by the Provincial Health Directorates within the framework of the Waste Management Regulation published in the official gazette dated 02.04.2015 and numbered 29314.

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	X		The procedures are carried out by the Department of Analysis and Control Laboratories on the samples, taken from medical products seized and confiscated as a result of judicial and administrative inspections. The samples are analysed by the Forensic Medicine Institution. In addition, the provisions of the Law No. 1262 on Pharmaceuticals and Medicinal Preparations and the Law No. 6197 on Pharmacists and Pharmacies are applied.
• where no criminal proceedings are anticipated to take place and the product is not being returned to the owner	X		

Answer to question 4:

Sampling is not carried out in the Department of Analysis and Control Laboratories. Acceptance processes of samples sent for analysis from the relevant departments of our institution are carried out according to the documents defined in our Quality Management System, the definition of the process is defined in the "Regulation on the Duties, Authorities

and Responsibilities with Working Principles and Procedures of the National Control Laboratory of the Turkish Medicines and Medical Devices Agency".

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	X		The disposal of the samples is carried out in accordance with the Articles 12 and 13 of the Regulation on the Implementation of the Law on Forensic Medicine Institution. In the relevant articles, it is also included explanations regarding the return of some of the samples to the sending institution and organization.
• return to the authority/service that provided the samples to the laboratory	X		

Answer to question 5:

The disposal process of unused samples in the Department of Analysis and Control Laboratories is carried out in accordance with the conditions specified in the "Regulation on the Duties, Authorities and Responsibilities with Working Principles and Procedures of the National Control Laboratory of the Turkish Medicines and Medical Devices Agency" and the documents defined in the Quality Management System.

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	X		According to the Article 12 of the Regulation on the Implementation of the Law on the Forensic Medicine Institution, the disposal procedures are carried out by the Department of Specialization in Chemistry. A disposal commission is established and safe disposal procedures are carried out.
• Do the rules or procedures apply where the products are disposed of by incineration or landfill dumping by the authority/service	X		
• Do the rules or procedures apply where the disposal is contracted out to an authorised/licensed environmental disposal contractor	X		

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?			
• Is the donation permitted to institutions for the purpose of training and research?			
• 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?			

Answer to question 6:

For medical devices, there is no regulation within our Agency in this context, and it is thought that it would be more appropriate to obtain information on the subject from the Ministry of Trade, Ministry of Internal Affairs, Ministry of Justice, Ministry of Environment, Urbanization and Climate Change.
For medicines; disposal operations are carried out by authorized/licensed environmental disposal companies in accordance with the relevant court decisions and by the Provincial Health Directorates within the framework of the Waste Management Regulation published in the official gazette dated 02.04.2015 and numbered 29314.

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			
• Is there monitoring based on reports of injuries or environmental damage done			

Answer to question 7:

There is no regulation within our Agency in this context, and it is thought that it would be more appropriate to obtain information on the subject from our Ministry's General Directorate of Public Health, Ministry of Commerce, Ministry of Internal Affairs, Ministry of Justice, Ministry of Environment, Urbanization and Climate Change .

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?		X	

Answer to question 8:
There is no training program organized by us regarding the processing of seized and confiscated medical products.

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		X	
• Do the training programmes include the prevention of instrumentalities used in the counterfeiting of medical products from being recycled and returned to the market			

Answer to question 9:
There is no training program organized by us regarding the processing of medical products that are the subject of a crime determined under the MEDICRIME Convention.

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?	X		The collection of products, found to be in violation of the legislation, from distribution channels is assigned to the authorized institutions. Disposal operations are carried out in accordance with the Regulation on Hazardous Waste Control. Hazardous wastes are prevented from being discharged directly or indirectly into the receiving environment in a way that harms human health and the environment from generation to final disposal. At every stage of waste management, the responsible persons are obliged to take measures to prevent harm to the environment and human health.
• Are there measures in place and checks on their effectiveness for the personal safety of officials coming into contact with such products	X		
• 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?	X		
• 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	X		

Answer to question 10:
There is no regulation within our Agency for medical devices in this context. For medicines, the duties, authorities, responsibilities and organizational structure of the Turkish Medicines and Medical Devices Agency are regulated in the Thirty-sixth Chapter of the Presidential Decree No. 4 on the Organization of Affiliated, Related, Associated Agencys and Organizations and Other Agencys and Organizations to Ministries, published in the Official Gazette No. 30479 dated 15.07.2018.
The duties and responsibilities included in the relevant decree are carried out by relevant and various laws. These laws are:

- Pharmaceutical and Medical Preparations Law No. 1262
- Turkish Penal Code No. 5237
- Law No. 984 on Pharmaceutical Businesses
- Law No. 5326 on Misdemeanors
- Customs Law No. 4458
- Anti-Smuggling Law No. 5607