COUNCIL OF EUROPE

1949 - 2024

CONSEIL DE L'EUROPE

T-MED (2024) 05

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	
Name of the person making the submission	
Position	
e-mail	
Mobile phone number	

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	
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)			
• Detained active substances (Art 4.c)			
• Detained excipients (Art 4.d)			
• Detained accessories (Art. 4.f)			
• Detained “parts” and “materials” (Art. 4.g)			
• Seized medical products (Art 4.a)			
• Seized active substances (Art 4.c)			
• Seized excipients (Art 4.d)			
• Seized accessories (Art. 4.f)			
• Seized “parts” and “materials” (Art. 4.g)			
• confiscated of medical products (Art 4.a)			
• confiscated active substances (Art 4.c)			
• Confiscated excipients (Art 4.d)			
• 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)			
• Detained active substances (Art 4.c)			
• Detained excipients (Art 4.d)			
• Detained accessories (Art. 4.f)			
• Detained “parts” and “materials” (Art. 4.g)			
• Seized medical products (Art 4.a)			
• Seized active substances (Art 4.c)			
• Seized excipients (Art 4.d)			
• Seized accessories (Art. 4.f)			
• Seized “parts” and “materials” (Art. 4.g)			
• confiscated of medical products (Art 4.a)			
• confiscated active substances (Art 4.c)			
• Confiscated excipients (Art 4.d)			
• 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?			
• permitting final disposal only with the consent of the owner or with a court confiscation order			
• Concerning security and storage where no final disposal consent is provided and the products cannot be returned to the presumed owner?			

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			
• where no criminal proceedings are anticipated to take place and the product is not being returned to the owner			

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			
• return to the authority/service that provided the samples to the laboratory			

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			
• Do the rules or procedures apply where the products are disposed of by incineration or landfill dumping by the authority/service			
• Do the rules or procedures apply where the disposal is contracted out to an authorised/licensed environmental disposal contractor			

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?			

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			

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?			

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

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?			
• Are there measures in place and checks on their effectiveness for the personal safety of officials coming into contact with such products			
• 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?			
• 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			