Nr. Rg02-002617 din 30.05.2025

Secretariat of the MEDICRIME Committee
email: medicrime@coe.int

Ministry of Foreign Affairs of the Republic of Moldova

Medicines and Medical Devices Agency, is pleased to enclose the response to the Questionnaire for the 2nd thematic monitoring round: Deposit and destruction measure of seized counterfeit medical products, active substances, excipients, parts, materials, and accessories, Phase 1, adopted by the MEDICRIME Committee on 22 November 2024.

Enclosure: Questionnaire for the 2nd thematic monitoring round, Phase 1 – 5 pages

General director

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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	Republic of Moldova

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	Responsible for collecting the replies to the questionnaire was designated Medicines and Medical Devices Agency.
Name of civil society contributing to the responding to the questionnaire	n/a
Name of other external contributors to the responding to the questionnaire	n/a

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)	■		In the Republic of Moldova is in place Order No. 9 by the Ministry of Health of (2006) "On the harmless destruction of medicines with expired expiry date, counterfeit, with quality deficiencies or without documents of origin (accompanying)" which regulates safe handling by Medicine and Medical Devices Agency of detained, seized and confiscated medical products, active substances and excipients. Additionally, in Law No. 1456-XII on Pharmaceutical Activities (1993), art.11^3 (3) is stated that "In case of an emergency (alerts of the World Health Organization and the European Medicines Agency, quality notifications, notifications for the detection of counterfeit medicines and reporting of serious adverse reactions to the administration of medicines), in order to protect the health of the population, the Agency for Medicines and Medical Devices suspends the use of an authorized medicine on the territory of the Republic of Moldova and withdraws from the State Nomenclature the authorized medicine, but which has proved to be offensive."
• 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)		■	

Note: Legislation of the Republic of Moldova provides for the seizure and confiscation of goods (can include medical devices, accessories, "parts" and "materials") involved in customs offenses (can include medical devices). For instance, the Customs Code No. 95/2021 allows

for the sequestration of goods when offenders are unable to pay penalties or when goods are used to commit offences. Seized goods are evaluated and may be confiscated to ensure compliance with the law.

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?		■	There are no officially established regulations or alternative acceptable procedures. Generally, this is outlined in Customs Code No. 95/2021, Criminal Code No. 985/2002 and Criminal Procedure Code No. 122/2003.
• 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?		■	