The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

GENERAL OVERVIEW QUESTIONNAIRE ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

As adopted by the Bureau of the MEDICRIME Committee on 7 July 2020

Replies should be addressed to the MEDICRIME Committee Secretariat by **23 September 2020** (**medicrime@coe.int**)

Document prepared by the MEDICRIME Committee Secretariat

TABLE OF CONTENTS

I. INTRODUCTION

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health[1] (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force in January 2016, requires criminalisation of the manufacturing of counterfeit medical products, of the supplying, offering to supply and trafficking in counterfeit medical products, of the falsification of documents and of the unauthorised manufacturing or unauthorised supplying of medicinal products and of the placing on the market of medical devices which do not comply with conformity requirements. The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.

2. The Committee of the Parties to the Convention (also known as the "MEDICRIME Committee"), established to monitor whether Parties effectively implement the Convention, decided that:

> 1. *Following ratification and within six months from the entry into force of the MEDICRIME Convention in respect of the Party concerned, every Party to the Convention shall be required to reply to a questionnaire aimed at providing the MEDICRIME Committee with a general overview of its legislative practice, institutional framework and policies for the implementation of the Convention at the national, regional and local levels. Thereafter, the Parties should regularly inform the MEDICRIME Committee of any substantial changes to the situation described in their replies to the general overview questionnaire.*
>
> 2. *States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.*
>
> 3. *The secretariat shall compile the replies received and make them public on the Committee's website[2].*

3. 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 coordinate 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 questionnaire shall be detailed, as comprehensive as possible, answer*

[1] Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, CETS No. 211, Article 1, para. 2.
[2] MEDICRIME Committee's Rules of Procedure, Rule 24.

all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

4. *The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time-limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.*

5. *The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the Bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."*

4. The purpose of this general questionnaire is to collect information to provide the MEDICRIME Committee with an overview of the situation, which will constitute the general framework within which it will assess replies by Parties to the thematic questionnaire for the first monitoring round (see Rule 24 of the MEDICRIME Committee's Rules of Procedure).

II. PRELIMINARY REMARKS

5. The provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without necessarily following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.

6. Parties will be invited to update their replies to this general questionnaire when they will receive the next thematic questionnaire. Responses to a thematic questionnaire should therefore be interrelated and combined with the responses provided in the context of this questionnaire.

7. Parties are kindly requested to:

- specify which state body/agency was responsible for collecting the replies to this questionnaire and which state bodies/agencies (and, at the discretion of the country, where relevant, civil society and external contributors) contributed to responding to this questionnaire;

- answer the questions with regard to 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;

- answer the questions from a non-discriminatory perspective (for example, related to gender)[3], i.e. specifying, where relevant, whether and how measures for victims and/or offenders take into account gender-specific requirements;

- bear in mind that when replying to questions related to "internal law" reference should also be made to the relevant case law;

- provide, whenever questions/answers refer to it, the relevant text (or a summary) of legislation or other regulations in English or French;

- if some of the questions below correspond to questions put to Parties by other bodies of the Council of Europe or other organisations (whether or not these are governmental bodies), Parties may refer to their initials answers (by providing a link to the relevant replies or by copying their answers) and update the information where necessary.

- in responding to questions, if you agree, please provide a reference to the legal provision. If you do not agree, please provide an explanation.

III. GENERAL FRAMEWORK

Question 1: Definitions

a. Does the understanding of "medical product" under your internal law correspond to that set out in **Article 4, letter (a)**, i.e. "medicinal products and medical devices"?

Although the term "medical product" is not defined in national legislation, its interpretation under domestic law corresponds to Article 4(a) of the Medicrime Convention, meaning that it includes medicines and medical devices.

b. Does the understanding of "medicinal product" under your internal law correspond to that set out in **Article 4, letter (b)**, i.e. "medicines for human and veterinary use which may be:
   i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
   ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;
   iii. an investigational medicinal product"?

The definitions in national legislation for medicines for human or veterinary use correspond to those in the Convention.
The definition of a medicine in Law No. 95/2006 on health care reform refers only to medicine for human use (" Article 699 (1). Medicine :

[3] As envisaged in Art. 2 of the MEDICRIME Convention.

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."
In Regulation (EU) 2019/6, which is directly applicable, veterinary medicinal products, are referred to as" veterinary medicinal products" (Article 4(1)).
An investigational medicinal product is defined by national legislation (Article 3(2) of Law No. 95/2006, Article 21(d) of Order of the Minister of Public Health No. 904/2006, Article 3(2) of Order of the Minister of Health No. 905/2006) and European legislation (Article 2(5) of Regulation (EU) No. 536/2014). Delegated Regulation (EU) 2017/1569 and Regulation (EU) No. 536/2014 [Annex I, letter j)] use the term "experimental medicinal products for human use" (Article 2, point 3, and Article 3), which is also adopted in Order of the Minister of Health No. 3,390/2022 [Article 21, para. (2), Annex No. 1, point 9].
The Penal Code (Art. 357) uses the term "counterfeit medicines," which does not include medicinal products for clinical investigation or veterinary medicinal products.

c. Does the understanding of "active substance" under your internal law correspond to that set out in **Article 4, letter (c)**, i.e. "any substance or mixture of substances that is designated to be used in the manufacture of a medicine, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product"?

   Yes. The definition of the active substance can be found in Article 699(3) of Law No. 95/2006 (3. Active substance : Any substance or combination of substances used in the manufacturing of a medicinal product and which, through use in the manufacturing process, becomes an active ingredient of the respective product, intended to exert a pharmacological, immunological or metabolic action, or to making a medical diagnosis) and Article 4(3) of Regulation (EU) 2019/6.

d. Does the understanding of "excipient" under your internal law correspond to that set out in **Article 4, letter (d)**, i.e. "any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product"?

   Yes. The definition of the excipient can be found in Article 699(4) of Law No. 95/2006 for medicinal products for human use (4. Excipient : Any constituent of a medicine other than an active substance or a packaging material) and in Article 4(4) of Regulation (EU) 2019/6 for veterinary medicinal products.

e. Does the understanding of "medical devices" under your internal law correspond to that set out in **Article 4, letter (e)**, i.e. "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
iii. investigation, replacement or modification of the anatomy or of a physiological process;
iv. control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"?

Yes. Medical devices are defined by Regulation (EU) 2017/745 (Article 2(1)) and Regulation (EU) 2017/746 (Article 2(1)), both of which are directly applicable in Romania, as well as by Government Emergency Ordinance No. 46/2021 (Article 1(1) and (2)) and Government Emergency Ordinance No. 137/2022 (Article 1(1) and (2)).

f. Does the understanding of "accessory" under your internal law correspond to that set out in **Article 4, letter (f)**, i.e. "an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device"?

Yes, "accessory" is defined by Regulation (EU) 2017/745 (Article 2(2)) and Regulation (EU) 2017/746 (Article 2(4)), which are directly applicable in Romania.

g. Do the understanding of "parts" and "materials" under your internal law correspond to that set out in **Article 4, letter (g)**, i.e. "all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof"?

Our domestic legislation does not provide a definition of the terms "components" and "materials" of medical devices.

According to Regulation (EU) 2017/745 (Article 23):" Parts and components 1. Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation."

h. Does the understanding of "document" under your internal law correspond to that set out in **Article 4, letter (h)**, i.e. "any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof"?

Yes. Law No. 95/2006 (Article 699) on medicine and Regulation (EU) 2017/745, Regulation (EU) 2017/746 (Article 2(1)), Government Emergency Ordinance No. 46/2021, and Government Emergency Ordinance No. 137/2022, for medical devices, refer to all necessary documents.
Under Article 10 of Regulation (EU) 2017/745, manufactures are obligated to prepare and maintain documentation relating to medical devices in accordance with Article 10 of Regulation (EU) 2017/745. The technical documentation and, where applicable, its summary, which must be prepared by the manufacturer, shall be presented in a clear, organized, unambiguous, and easily searchable manner and shall include, in particular, the elements listed in Annex II thereof and the post-market surveillance documentation to be drawn up by the manufacturer in accordance with Articles 83–86 shall be presented in a clear, organized, unambiguous, and easily searchable, and includes, in particular, the elements listed in Annex III of Regulation (EU) 2017/745. The labeling and instructions for use shall be prepared in accordance with MDR Annex I, Chapter III of Regulation (EU) 2017/745. The information and documents shall be presented in accordance with Article 3 of Government Emergency Ordinance No. 46/2021 and Government Emergency Ordinance No. 137/2022 on the establishment of the institutional framework.
In light of the above, it can be concluded that the understanding of the term “document” corresponds to the definition provided for in Article 4(h) of the Medicrime Convention.

i. Does the understanding of “manufacturing” under your internal law correspond to that set out in **Article 4, letter (i)**, i.e.
    i. “as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;
    ii. as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;
    iii. as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state”?

Yes. The manufacture of medicines, active substances, and excipients is regulated by Law No. 95/2006 (Article 699, paras. 41 and 43, and Chapter IV) as well as by the Principles and Guidelines of Good Manufacturing Practice for Medicinal Products for Human Use, including those for clinical trials, approved by Order of the Minister of Health No. 905/2006 and Delegated Regulation (EU) 2017/1569.
According to Regulation (EU) 2017/745 (Article 10 (1) –” When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.”
According to Regulation (EU) 2017/745 (Article 2 (30) –” ‘manufacturer’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;”
Order of the President of the National Safety and Health Administration of Romania No. 86/2020 approving Sanitary veterinary norm laying down the principles and

guidelines of good manufacturing practice for veterinary medicinal products (transposes Commission Directive 91/412/EEC). This sanitary veterinary norm lays down the principles and guidelines of good manufacturing practice for veterinary medicinal products whose manufacture requires authorization in accordance with the provisions of Article 88 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. The detailed guidelines mentioned are set out in the Guide to Good Manufacturing Practice for medicinal products for human and veterinary use.
The manufacturing of veterinary medicinal products is governed by Chapter VI of Regulation (EU) 2019/6.

j. Does the understanding of "counterfeit" under your internal law correspond to that set out in **Article 4, letter (j)**, i.e. "a false representation as regards identity and/or source"?
Yes. The Romanian legislation uses the term" falsified medicine" as defined in Article 699 (40) - "40. falsified medicine —any medicine that is falsely presented as to: a) its identity, including its packaging and labelling, name, or composition with respect to any of its ingredients, including excipients and the concentration of those ingredients; b) the source, including the manufacturer, country of manufacture, country of origin, or marketing authorization holder; or c) the history, including records and documents relating to the distribution channels used." Furthermore, pursuant to Article 699(40) of Law No. 95/2006, the term "falsified medicine" also includes excipients; however, Law No. 95/2006 applies only to industrially manufactured medicine for human use.
This definition does not include unintentional quality nonconformities and does not refer to infringements of intellectual property rights.
'Falsified veterinary medicinal product' is defined in Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
'Falsified active substance used as a starting material in veterinary medicinal products' is defined in Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021 as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. For medicines, the term "falsified" is also found in Article 761(f) and (g), Article 935(1)(i) and (k), Article 772(1), Article 775((3)(ii) and (4), Article 803(d), and Article 866(2) of Law No. 95/2006.
The Criminal Code: includes the concept of a counterfeit medicine, which may imply a violation of intellectual property rights; does not criminalize counterfeit medicine for clinical trials, components, or materials; uses the general concept of" medicines" the scope of which is determined by reference to special (sector specific) legislation.
According to Article 2(9) of Regulation (EU) 2017/745, "falsified device" means any device for which its identity and/or source and/or its CE marking certificates or documents relating to CE marking procedures are falsely presented. This definition does not include unintentional non-conformities and is without prejudice to infringements of intellectual property rights;
The definition in Regulation (EU) 2017/745 refers to a "counterfeit device," while Article 4(j) of the Medicrime Convention refers to the term "counterfeit," but this includes

elements that falsely represent its identity and/or source, which corresponds to the definition in the Medicrime Convention.
With regard to the falsification of medical devices or the sale, supply, or other operations involving the circulation of such devices, Law No. 95/2006, through Article 935(i) and (k), classifies the distribution or use of falsified medical devices in the course of professional activities as administrative offenses. Furthermore, Government Emergency Ordinance No. 46/2021 establishes administrative offenses regarding the placing on the market of non-compliant medical devices under Article 28(a)-(e) a)-e) and Article 28(j) and (k), respectively (corresponding to Article 13 and 14 of Regulation (EU) 2017/745). Therefore, at this time, domestic legislation does not include criminal offenses related to medical devices, but only administrative offenses.
If, as a result of the inspections carried out, medical devices suspected of being falsified, as defined in Article 2(9) of Regulation (EU) 2017/745, are identified, action shall be taken in accordance with the internal procedures of the competent authority, the National Agency for Medicines and Medical Devices of Romania (NAMMDR). In cases of suspected non-compliance or falsification, confirmation is requested from the competent authority where the manufacturer or the manufacturer's authorized representative is established, through compliance exchange forms initiated by Romania.
In the event that medical devices are found to be non-compliant, the applicable legal provisions shall be enforced in accordance with NAMMDR procedures; and in the event that counterfeiting is confirmed, NAMMDR shall report the information to the criminal investigation authorities for investigation regarding the commission of the crime of forgery.
In the event that other competent authorities in the field of medical devices bring to the attention of NAMMDR information regarding counterfeit Certificates of Conformity (CE), after NAMMDR verifies the existence within Romania of the counterfeit certificate or a counterfeit copy of a CE issued by a notified body, the information shall be posted on the NAMMDR website.

k. Does the understanding of "victim" under your internal law correspond to that set out in **Article 4, letter (k)**, i.e. "any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8"?
Yes, in accordance with Law No. 211/2004 on certain measures to ensure the provision of information, support, and protection to victims of crime (Article 34) and the Code of Criminal Procedure (Article 79).

Question 2: Non-discrimination

Is discrimination, on grounds such as the ones mentioned in the indicative list in **Article 2**, prohibited in the implementation of the Convention, in particular in the enjoyment of the rights guaranteed by it? If so, please specify. If not, please justify.

Yes.

 Constitution of Romania (Article 4 para (2) Unity of the people and equality among citizens and art. 16 Equality of rights) ;

 Government Ordinance No. 137/2000 on the prevention and punishment of all forms of discrimination (republished), as approved by Law No. 48/2002 (Article 2, para. (1)) ;

 Law No. 202/2002 on Equal Opportunities and Equal Treatment for Women and Men. Regulates equality between women and men.

 Law No. 211/2004 on Certain Measures to Ensure the Information, Support, and Protection of Victims of Crime;

 The Romanian Penal Code prohibits certain acts motivated by hatred or discrimination, including: incitement to hatred or discrimination, abuse of authority through discrimination, crimes motivated by prejudice.

 Law no. 95/2006 on Healthcare Reform, republished, as amended: ensures access to medical services without discrimination (Article 663(2), Article 902(1)(f));

 Law No. 46/2003 on Patients' Rights: Guarantees the patient's right to quality medical care, without discrimination based on race, sex, age, religion, political views, etc. (Article 1(b), Article 3, Article 27).

Question 3: Overview of the implementation

Please indicate (without entering into details):

a. the main legislative or other measures to combat counterfeiting of medical products and similar crimes involving threats to public health in accordance with the Convention;

 Law no. 95/2006 on Healthcare Reform, republished, as amended;
 The Criminal Code;
 The Government Emergency Ordinance no. 46/2021 on the establishment of the institutional framework and measures for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
 The Emergency Ordinance no. 137/2022 on establishment of the institutional framework, as well as the measures necessary for the implementation of the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
 Law No. 143/2000 on the prevention and fight against illicit drug trafficking and consumption;
 Law No. 104/2008, on the prevention and combating of illicit production and traffic of doping substances with high risk ;
 Law no. 194/2011 on combating operations with products likely to have psychoactive effects, other than those provided for by normative acts in force ;

 Government Decision No. 984/2005 on the establishment and sanctioning of contraventions to the veterinary sanitary and food safety standards ;

 Government Ordinance no. 42/2004 on the organization of sanitary-veterinary and food safety activities ;

 The Romanian Customs Code ;

 Pursuant to Article 1(2) of Order No. 502/2013 of the Minister of Health approving the requirement for monthly reporting on the placing on the market in Romania and the sales of medicinal products for human use by authorized wholesalers, importers, and manufacturers, as subsequently amended and supplemented: " (2) The ultimate purpose of reporting is to ensure the traceability of medicines throughout the entire supply chain, from manufacturing and/or distribution to the level of community pharmacies, hospital pharmacies, and drugstores; to verify the correct dispensing of prescription and over-the-counter medicines; to detect counterfeit medicines and prevent their entry into the authorized distribution network, to combat the existence of illegal parallel channels for the sale of medicines, and to ensure the rapid recall of non-compliant batches of medicines or in cases of public health emergencies."

We note that NAMMDR processes/saves the monthly reports submitted in accordance with Order of the Minister of Health No. 502/2013 by creating monthly databases to verify the traceability of medicines throughout the supply chain and to combat the existence of illegal parallel channels for the sale of medicines.

b. whether your country has adopted a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health. If so, please specify the main fields of action and the body/bodies responsible for its/their implementation;

Romania has not adopted a separate national strategy or an action plan dedicated exclusively to combating the counterfeiting of medical products and similar crimes that pose threats to public health. However, relevant institutional mechanisms, legislative measures, and operational systems have been implemented, such as the SPOC network, the National Medicines Verification System (SNVM), the activities of the SARMF within NAMMDR, and participation in European and international initiatives in this field.

The National Strategy against Organized Crime 2021–2024, approved by Government Decision No. 930/2021, aims to:

1. Preventing the introduction of falsified medicines into the market: control of the pharmaceutical supply chain, verification of medicine authenticity; traceability and serialization. Responsible institutions: the National Agency for Medicines and Medical Devices of Romania, distributors and pharmacies (through the EU medicine verification system), Ministry of Health;
2. Combating organized crime and illicit drug trafficking: investigating smuggling and counterfeiting networks, police and judicial operations, criminal prosecution of offenses. Responsible institutions: Romanian Police, Directorate for Investigating Organized Crime and Terrorism, Prosecutor's Office attached to the High Court of Cassation and Justice;

3. Customs control and prevention of illegal imports: detection of counterfeit medicines at the border, inspection of parcels and shipments, international customs cooperation. Responsible institutions: Romanian Customs Authority, Border Police;
4. Monitoring, alerting, and pharmacovigilance: identification of suspicious medicines; incident reporting; management of rapid alerts at the national and European levels. Responsible institutions: Romanian National Agency for Medicines and Medical Devices of Romania, European pharmacovigilance networks.
5. International cooperation and assistance programs: participation in EU and international projects; training of authorities in third countries; exchange of information and best practices. Responsible institutions: Ministry of Internal Affairs, Ministry of Health, National Agency for Medicines and Medical Devices of Romania, distributors and pharmacies, European cooperation bodies (e.g., Europol, CEPOL).
6. Regulation and legislative harmonization: transposition of EU legislation on counterfeit medicines, strengthening of the criminal and administrative framework, regulation of pharmaceutical distribution. Responsible institutions: Romanian Parliament, Romanian Government, Ministry of Health, Ministry of Justice.
Government Decision No. 1,269/2021 approving the National Anti-Corruption Strategy for 2021–2025 and related documents. Specific Objective 4.1. – Enhancing integrity, reducing vulnerabilities, and mitigating corruption risks in the public health system
Strengthening the traceability mechanism for medicines on the Romanian market – ratification of the Medicrime Convention.

c. If there has not been any adoption of a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health, whether there is a strategy and /or Action Plan by a particular Ministry or State Agency that leads on this nationally.

Question 4: National co-operation and information exchange

a. Please describe how co-operation and exchange of information is ensured between representatives of health authorities, law-enforcement (e.g. police and customs authorities) and other competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health (**Article 17, para. 1**);

Experts from the Romanian National Agency for Medicines and Medical Devices of Romania have been appointed as:
- the National Focal Point for the WHO Global Focal Point Network for substandard and falsified (SF) medical products;
- experts in the Working Group of Enforcement Officers (WGEO) organized within the Heads of Medicines Agencies (HMA);
- experts in the Committee of Experts on Minimizing Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED);
- experts at EU institutions in technical working groups in the field of pharmaceuticals and medical devices

- Counterfeit medicines - Point 4 of Annex No. 2 to Order of the Minister of Health No. 1 474/2021 on the establishment and operation of technical expert groups responsible for developing technical opinions on documents under discussion at the European level and ensuring representation at meetings of the working bodies of the European Union institutions, as subsequently amended and supplemented;
- The Expert Group on the Delegated Act on Safety Features for Medicinal Products for Human Use within the European Commission.

In order to implement the measure set forth in the Action Plan for the National Strategy against Organized Crime 2021–2024 and to conduct an impact assessment of the ratification of the Medicrime Convention and to ratify it, a working group was established comprising representatives from the Ministry of Foreign Affairs, the Ministry of Justice, the Directorate for Investigating Organized Crime and Terrorism (DIICOT), the General Inspectorate of the Romanian Police, the Ministry of Health, and NAMMDR.
In 2010, the General Inspectorate of the Romanian Police and the National Agency for Medicines and Medical Devices (ANMDM) signed a cooperation agreement aimed at combating the counterfeiting of medicines for human use.
On July 7, 2022, a cooperation agreement was signed between NAMMDR and the Romanian Medicines Serialization Organization (OSMR). This Agreement underscores the importance that both organizations place on the National Medicines Verification System (SNVM), whose purpose is to prevent counterfeit medicines from entering the legal supply chain, thereby ensuring patients' access to authentic medicines.
Cooperation between NAMMDR and the Romanian Customs Authority aims to verify the legality of imports and prevent non-compliant products from entering the market, and serves as a critical pillar in securing the legal supply chain. It combines the physical border controls carried out by the Romanian Customs Authority with NAMMDR's technical and regulatory expertise.
NAMMDR issues a customs clearance certificate only for medical devices that will be used within Romania, in one of the following situations:
a) medical devices intended for technical evaluation, clinical investigation, and/or performance evaluation for the purpose of certification;
b) devices imported as samples for trade fairs, exhibitions, or other promotional events.
NAMMDR and Customs collaborate to intercept postal packages containing medicines purchased from unauthorized online sources, the riskiest distribution channel.
OSMR recently launched the campaign "Counterfeit Medicines Can Kill!" and the platform medicamentesigure.ro to educate the public about purchasing medicines exclusively from licensed sources.
In March 2026, OSMR and NAMMDR launched the national campaign "Counterfeit Medicines Can Kill!", a broad public information and awareness initiative aimed at drawing public attention to the serious risks associated with the use of counterfeit medicines.

b. Is any form of cooperation between the competent authorities and the commercial and industrial sectors promoted as regards risk management of counterfeit medical products and similar crimes involving threats to public health? (**Article 17, para. 2**)

The Romanian Medicines Serialization Organization serves as the administrative body for the National Medicines Verification System (SNVM) vis-à-vis the competent authorities in Romania, in accordance with the provisions of Article 1, paragraph (3)(b) of the Detailed Rules on Safety Features Appearing on the Packaging of Medicinal Products for Human Use, approved by Order of the Minister of Health No. 1473/2018, in application of Commission Delegated Regulation (EU) 2016/161 of October 2, 2015, supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for safety features appearing on the packaging of medicinal products for human use
SNVM is a verification platform through which pharmacies or other interested parties, such as wholesale distributors in Romania, can verify the authenticity of a product.
Steps have been taken regarding cooperation with The National Authority for Administration and regulation in Communications, coordinator of digital services in Romania according to Article 49 (2) Digital Services Act and The National Audiovisual Council which plays a key role in combating the promotion of falsified medicines, is responsible for monitoring and penalizing misleading advertising of such products in the media.

c. Which legislative or other structured measures have been taken to set up or strengthen mechanisms for:
    - receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health? (**Article 17, para. 3, letter (a)**);

NAMMDR is the competent authority responsible for monitoring the safety and quality of medical products, serving as the national contact point. NAMMDR has created the "Crime Medicine" platform, a portal dedicated exclusively to reports of counterfeit/falsified medicines, where patients and healthcare professionals can report suspicions (email: contrafacere@anm.ro).
NAMMDR, OSMR, and the Romanian Association of International Medicines Manufacturers (ARPIM) collaborate to organize awareness campaigns, such as " Falsified Medicines Can Kill!".
Romanian authorities (police, customs) participate in international operations (e.g., Operation Pangea) to seize counterfeit medicines and shut down illegal websites.

    - making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them? (**Article 17, para. 3, letter (b)**);

NAMMDR collaborates with the Romanian Police (particularly specialized units, such as those combating organized crime) and the Customs Authority to seize and investigate counterfeit products, including through international operations (e.g., INTERPOL).
As of February 9, 2019, Romania has been using the SNVM, which allows for the verification of the authenticity of each medicine package by scanning its safety features.

The “Crime Medicine” platform—NAMMDR provides a dedicated section for reporting counterfeit/falsified medicines, where information is centralized and forwarded to the competent authorities (email: contrafacere@anm.ro).
Notification via Eudamed - information on medical devices is recorded in the national database and linked to Eudamed (the European database on medical devices), facilitating authorities’ access to data on manufacturers and products.
Manufacturers and distributors have a legal obligation to immediately inform NAMMDR and the marketing authorization holder (MAH) if they suspect that medicines are counterfeit.
If a counterfeit is detected, NAMMDR notifies the Customs Authority and criminal investigation bodies to stop the entry/distribution of the products into the legal supply chain. Customs inspects imports and blocks suspicious goods at the border based on alerts from NAMMDR system.

d. Please indicate the persons, units or services in charge of this co-operation and information exchange in the field of the MEDICRIME Convention. Please indicate how they are trained for this purpose and how resources are secured for it/them (**Article 17, para. 4**);
National Agency for Medicines and Medical Devices of Romania – Falsified Drug Alerts Service and Legal and External Affairs Department – training by EDQM/WGEO/Europol/WHO.

Romanian Police – the Directorate for Combating Organized Crime (DCCO) within the Romanian Police receives ongoing professional training in combating organized crime, including online crime, and collaborates with international agencies (Europol/Interpol) on investigative techniques.

Question 5: International cooperation

a. Please indicate the national contact point responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health (**Article 22, para. 2**).

National Agency for Medicines and Medical Devices of Romania.

b. Has your country integrated prevention and the fight against counterfeiting of medical products and similar crimes involving threats to public health in assistance programmes for development provided for the benefit of third states (**Article 22, para. 3**)? Please give examples.

With the support of the United Nations Interregional Crime and Justice Research Institute (UNICRI), in 2014 Romania was among the first countries in the region to sign an operational protocol for a joint task force to combat counterfeit medicines. The project benefited from the direct expertise of regulatory agencies in Italy (AIFA) and the United Kingdom (MHRA).

Romania participates in coordinated efforts to combat the counterfeiting of medicines and medical devices, including through cross-border cooperation and international programs

Operation Pangea (Operation Pangea XVIII, took place from March 10–23, 2026): Romania participated alongside 90 other countries in a large-scale global operation coordinated by Interpol. The operation aimed to dismantle pharmaceutical crime networks and resulted in the seizure of over 6.4 million doses of unauthorized and counterfeit medicines. As part of this cooperation, Romanian authorities monitored online platforms and messaging apps used to illegally introduce dangerous medical products into the European market.

IV. PROSECUTION OF PERPETRATORS OF COUNTERFEIT OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 6: Criminal Law offences

a. Please indicate whether the intentional conducts in the box below are considered criminal offences in internal law.

b. Do the offences in your internal laws require intentional conduct? If no, please provide information. Yes

c. Please highlight whether there are any other offences not included in the box below that involves counterfeit of medical products and similar crimes involving threats to public health in your country? Please provide their definitions and specify in which act these are included;

Article 5 – Manufacturing of counterfeits PARTIALLY

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.

Article 6 – Supplying, offering to supply, and trafficking in counterfeits PARTIALLY

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in

stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.*

Article 7 – Falsification of documents YES

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.*

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials*

Article 8 – Similar crimes involving threats to public health NO

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

a *the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:*

i *medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or*

ii *medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;*

b *the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.*

Article 9 – Aiding or abetting and attempt YES

1 *Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.*

2 *Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.*

3 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.*

Article 5 – Manufacturing of counterfeits

Criminal Code, Article 357 – Adulteration or Substitution of Food or Other Products

”(…)

(2) The preparation, offering, or display for sale of counterfeit or substituted medicines that are harmful to health shall be punishable by imprisonment for a term of 6 months to 5 years and the deprivation of certain rights.”

Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Criminal Code Article 358 - Marketing of counterfeit products

”(…)

(3) Selling medicines knowing that they are counterfeit, adulterated or with an expired validity period, if they are harmful to health or have lost their therapeutic efficacy in whole or in part, is punishable by imprisonment from one to 5 years and the prohibition of exercising certain rights.”

Criminal Code, Article 357 Adulteration or substitution of food or other products (…)

”(2) Preparing, offering or exposing for sale counterfeit or substituted medicines, which are harmful to health, is punishable by imprisonment from 6 months to 5 years and the prohibition of exercising certain rights.”

Article 7 – Falsification of documents

Criminal Code, Article 325 - Computer fraud

” The act of introducing, modifying or deleting, without right, computer data or of restricting, without right, access to such data, resulting in data that is not true, for the purpose of being used to produce a legal consequence, constitutes a crime and is punishable by imprisonment from one to 5 years.”

Criminal Code Article 322 - Forgery of documents under private signature

” (1) Forgery of a private document by any of the methods provided for in Article 320 or Article 321, if the perpetrator uses the forged document or entrusts it to another person for use, with a view to producing a legal consequence, is punishable by imprisonment from 6 months to 3 years or a fine.

(2) Attempt is punishable.”

Article 9 – Aiding or abetting and attempt

Criminal Code, Article 49 Punishment for participants

” The co-perpetrator, instigator and accomplice in a crime committed intentionally shall be punished with the punishment provided by law for the perpetrator. When determining the punishment, the contribution of each person to the commission of the crime, as well as the provisions of Article 74, shall be taken into account.”

Criminal Code, Article 32 Attempt

” (1) An attempt consists in the execution of the intention to commit the crime, execution which was however interrupted or did not produce its effect.

(2) There is no attempt when the impossibility of consummating the crime is the consequence of the way in which the execution was conceived.”

Criminal Code, Article 33 Punishment of attempt

” (1) An attempt shall be punished only when the law expressly provides for this.

(2) An attempt shall be punished with the punishment provided by law for the consummated crime, the limits of which shall be reduced by half. When the law provides for a life sentence for the completed crime, and the court would orient itself towards this, the attempt is sanctioned with a prison sentence of 10 to 20 years."

Question 7: Jurisdiction

With regard to the offences referred to in question 6, please indicate which jurisdiction rules apply. Please specify under which conditions, if required (**Article 10, Explanatory Report, paras. 69-78**).

Criminal Code, Article 8 Territoriality of Criminal Law

" (1) Romanian criminal law applies to offenses committed on the territory of Romania.

(2) The territory of Romania is understood to mean the land, territorial sea, and waters, including the soil, subsoil, and airspace, enclosed within the state borders.

(3) An offense committed on the territory of Romania means any offense committed on the territory referred to in paragraph (2) or on a vessel flying the Romanian flag or on an aircraft registered in Romania.

(4) An offense is considered to have been committed on the territory of Romania also when, on that territory or on a ship flying the Romanian flag or on an aircraft registered in Romania, an act of commission, instigation, or complicity was carried out, or the result of the offense occurred, even in part."

Criminal Code, Art. 9 Personal Jurisdiction of Criminal Law

" (1) Romanian criminal law applies to offenses committed outside the country's territory by a Romanian citizen or a Romanian legal entity, if the penalty provided for by Romanian law is life imprisonment or imprisonment for more than 10 years.

(2) In all other cases, Romanian criminal law applies to offenses committed outside the country's territory by a Romanian citizen or a Romanian legal entity if the act is also classified as an offense under the criminal law of the country where it was committed or if it was committed in a place not subject to the jurisdiction of any state.

(3) Criminal proceedings shall be initiated with the prior authorization of the Chief Prosecutor of the Prosecutor's Office attached to the Court of Appeal within whose territorial jurisdiction the Prosecutor's Office first notified is located or, as the case may be, of the Chief Prosecutor of the Prosecutor's Office attached to the High Court of Cassation and Justice. The period within which the prosecutor may issue the authorization is up to 30 days from the date of the request for authorization and may be extended, in accordance with the law, provided that the total duration does not exceed 180 days."

Criminal Code, Article 10 Scope of Criminal Law

" (1) Romanian criminal law applies to offenses committed outside the country's territory by a foreign national or a stateless person against the Romanian state, against a Romanian citizen, or against a Romanian legal entity.

(2) Criminal proceedings may be initiated only with the prior authorization of the Prosecutor General of the Prosecutor's Office attached to the High Court of Cassation and Justice and only if the act is not the subject of judicial proceedings in the state on whose territory it was committed."

Criminal Code, Article 11 Universality of Criminal Law

” (1) Romanian criminal law applies to offenses other than those provided for in Article 10, committed outside the country’s territory by a foreign national or a stateless person who is voluntarily present on Romanian territory, in the following cases:

a) an offense has been committed that the Romanian state has undertaken to punish under an international treaty, regardless of whether or not it is provided for by the criminal law of the state on whose territory it was committed;

b) the extradition or surrender of the offender has been requested and refused.

(2) The provisions of paragraph (1)(b) shall not apply when, under the law of the state in which the offense was committed, there is a ground preventing the initiation of criminal proceedings, the continuation of criminal proceedings, or the enforcement of the sentence, or when the sentence has been served or is deemed to have been served.

(3) When the sentence has not been served or has been served only in part, the procedure shall be in accordance with the legal provisions regarding the recognition of foreign judgments.”

Law No. 302/2004 on International Judicial Cooperation in Criminal Matters. - Article 23 Transfer of Criminal Proceedings in Cases of Refusal of Extradition

” (1) The refusal to extradite its own citizen or a political refugee obliges the Romanian State, at the request of the requesting State, to refer the case to its competent judicial authorities so that criminal prosecution and trial may be conducted, if appropriate. To this end, the requesting State shall transmit, free of charge, to the Romanian Ministry of Justice the case files, information, and evidence pertaining to the offense. The requesting State shall be informed of the outcome of its request. (…)”

Question 8: Corporate liability

Does your system provide that a legal person may be held liable for an offence established in accordance with **Article 11**? Please specify under which conditions.

Criminal Code, Article 17 Commission of an Offence by Omission

” An offence implying the occurrence of a result is also considered committed by omission when:

a) there is a legal or contractual obligation to act;

b) the perpetrator of the omission, through a prior act or inaction, has created a state of danger for the protected social value that facilitated the occurrence of the result.”

Criminal Code, Article 135 Conditions for the Criminal Liability of Legal Entities

” (1) A legal entity, with the exception of the State and public authorities, is criminally liable for offenses committed in the course of its business activities or in the interest of or on behalf of the legal entity.

(2) Public institutions are not criminally liable for offenses committed in the exercise of an activity that cannot be the subject of the private sector.

(3) The criminal liability of a legal entity does not exclude the criminal liability of the natural person who contributed to the commission of the same act.”

Question 9: Sanctions and measures

a. Please indicate which sanctions internal law provides for the criminal offences established in accordance with the Convention with regard to both natural and legal persons. Please specify whether the sanctions are criminal, civil and/or administrative sanctions (**Article 12, Explanatory Report, paras. 84-91**);

Criminal Code, Article 357 – Adulteration or Substitution of Food or Other Products

" (1) The preparation, offering, or display for sale of counterfeit or substituted food, beverages, or other products, if harmful to health, is punishable by imprisonment for a term of 3 months to 3 years or by a fine and the deprivation of certain rights.

(2) The preparation, offering, or display for sale of counterfeit or substituted medicines that are harmful to health shall be punishable by imprisonment for a term of 6 months to 5 years and the deprivation of certain rights."

b. Which legislative or other measures have been taken to provide for the possibility of taking into account final sentences passed by another Party in relation to the offences established in accordance with the Convention? Please provide details and describe any good practice resulting from the taking of these measures (**Article 14, Explanatory Report, paras. 100-105**).

Criminal Code, Article 41 Recidivism

" (…)

(3) In determining whether a person is a repeat offender, a conviction handed down abroad for an offense also covered by Romanian criminal law shall be taken into account, provided that the conviction has been recognized in accordance with the law."

Question 10: Aggravating Circumstances

Please indicate which of the circumstances referred to in **Article 13**, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of internal law, be taken into consideration in your legal system as aggravating circumstances in the determination of the sanctions in relation to the offences established in accordance with this Convention (**Explanatory Report, paras. 92-99**).

Criminal Code, Article 192 Manslaughter

" (1) Manslaughter is punishable by imprisonment for a term of one to five years.

(2) Negligent homicide resulting from failure to comply with legal provisions or safety measures required for the practice of a profession or trade or for the performance of a specific activity shall be punishable by imprisonment for a term of 2 to 7 years. When the violation of legal provisions or precautionary measures constitutes a crime in itself, the rules regarding concurrent offenses shall apply.

(3) If the act committed has caused the death of two or more persons, the special limits of the penalty provided for in para. (1) and para. (2) shall be increased by half."

Criminal Code, Article 41 Recidivism

" (1) Recidivism occurs when, after a conviction to a prison sentence of more than one year has become final and until rehabilitation or the expiration of the rehabilitation period, the

convicted person intentionally or with excessive intent commits another offense for which the law prescribes a prison sentence of one year or more.
(2) Recidivism also applies if one of the penalties provided for in paragraph (1) is life imprisonment.
(3) In determining recidivism, a conviction rendered abroad for an offense also covered by Romanian criminal law shall be taken into account, provided that the conviction has been recognized in accordance with the law."
Criminal Code, Article 367 Formation of an organized criminal group
" (1) Initiating or forming an organized criminal group, joining or supporting, in any form, such a group is punishable by imprisonment from one to 5 years and the prohibition of exercising certain rights.
(2) When the crime that falls within the scope of the organized criminal group is sanctioned by law with a life sentence or imprisonment for more than 10 years, the punishment is imprisonment from 3 to 10 years and the prohibition of exercising certain rights.
(3) If the acts provided for in para. (1) and para. (2) were followed by the commission of a crime, the rules regarding concurrent crimes shall apply. (…)"
Criminal Code, Article 196 Negligent bodily injury
" (1) The act provided for in art. 193 paragraph (2) committed through negligence by a person under the influence of alcoholic beverages or a psychoactive substance or in the performance of an activity that constitutes an offense in itself is punishable by imprisonment from 3 months to one year or a fine.
(2) The act provided for in art. 194 paragraph (1) committed through negligence is punishable by imprisonment from 6 months to 2 years or a fine.
(3) When the act provided for in para. (2) was committed as a result of failure to comply with the legal provisions or precautionary measures for the exercise of a profession or trade or for the performance of a certain activity, the punishment is imprisonment from 6 months to 3 years or a fine.
(4) If the consequences provided for in para. (1) - (3) have occurred against two or more persons, the special limits of the penalty shall be increased by one third.
(5) If the failure to comply with the legal provisions or the precautionary measures or the performance of the activity that led to the commission of the acts provided for in para. (1) and para. (3) constitutes in itself a crime, the rules regarding the concurrence of crimes shall apply.
(6) The criminal action shall be initiated upon the prior complaint of the injured person."

Question 11: Investigations and criminal measures

a. Which legislative or other measures have been taken to ensure that investigations or prosecutions of offences established in accordance with the Convention shall not be subordinate to a complaint and that the proceedings may continue even if the victim has withdrawn his or her statement? (**Article 15, Explanatory Report, para. 106**).

   Code of Criminal Procedure, Article 7 Obligation to Initiate and Prosecute Criminal Proceedings
   " (1) The prosecutor is obligated to initiate and conduct criminal proceedings ex officio when there is evidence indicating that a crime has been committed and there is no legal impediment, other than those provided for in paragraphs (2) and (3).
   (2) In the cases and under the conditions expressly provided by law, the prosecutor may refrain from prosecuting if, in light of the specific facts of the case, there is no public interest in achieving the purpose of the prosecution.

(3) In cases expressly provided for by law, the prosecutor shall initiate and conduct criminal proceedings after the filing of a prior complaint by the injured party or after obtaining authorization or a referral from the competent authority or after fulfilling another condition provided for by law."

b. Please indicate the persons, units or services or other formalised or agreed arrangements in charge of criminal investigations in the field of MEDICRIME Convention. Please indicate how specialisation in this field is achieved and how resources are secured for it/them (**Article 16, para. 1, Explanatory Report, paras. 107-110**).

In Romania, the investigation of these facts is shared depending on the complexity and form of organization of the crime between:
- the Judicial Police, the Directorate for the Investigation of Economic Crime (DICE) - is the main structure that coordinates and carries out criminal investigations regarding illegal commercial circuits, fraud with medicines or medical devices and the counterfeiting of pharmaceutical brands;
- the Directorate for Combating Organized Crime (DCCO) - the Service for Combating Cybercrime/Macrocrime - takes over the criminal investigation when the counterfeiting or distribution of dangerous medical products is carried out by an organized criminal group or through illegal markets on the internet (Dark Web/clandestine online platforms);
- Prosecutors' offices: DIICOT (Directorate for the Investigation of Organized Crime and Terrorism) - leads and supervises the criminal investigation in complex cases of cross-border organized crime (e.g. networks that import counterfeit active substances from Asia, package them in Romania and distribute them in the EU)
- Prosecutors' offices attached to courts or magistrates' courts: Handles local, specific cases (e.g. individual doctors or pharmacists who introduce counterfeit products into circulation).

Specialization focuses exclusively on the tactics and techniques of investigating this specific type of crime through:
- Specific training of prosecutors and police officers: through the National Institute of Magistracy (INM) and police schools, seminars are organized focused on techniques for investigating pharmaceutical crime. Investigators are trained to understand the legal distribution chain (to detect loopholes) and minimal medical/pharmaceutical terminology.
- Training in special investigative techniques: specialization includes the mandatory use of methods provided for by the Code of Criminal Procedure and recommended by the Convention: controlled deliveries (letting a shipment of counterfeit medicines cross the border to identify the complete network), the use of investigators with protected identities (for test purchases from illegal online pharmacies) and the interception of encrypted communications.
- Participation in international "Task Force" type operations: the practical specialization of Romanian investigators is achieved through direct involvement in annual operational actions coordinated by Europol and Interpol (such as Operation PANGEA). This gives judicial police officers direct access to state-of-the-art forensic methodologies used by other states. The resources necessary to successfully complete a criminal

investigation are provided by: the state budget, technical logistics for cyber investigations: the free technical support mechanism from brand owners (pharmaceutical companies, victims of counterfeiting).

c. Please describe under which circumstances carrying out financial investigations, the use of covert operations, of controlled delivery and of other special investigative techniques by authorities is allowed in relation to the investigation of the offences established in accordance with the Convention (**Article 16, para. 2**).

Code of Criminal Procedure - Article 138 General Provisions

" (1) The following constitute special methods of surveillance or investigation:

a) the interception of communications or any type of remote communication;

b) access to a computer system;

c) video, audio, or photographic surveillance;

d) location tracking or surveillance by technical means;

e) obtaining data regarding a person's financial transactions;

f) the detention, handover, or search of postal items;

g) the use of undercover investigators and informants;

h) authorized participation in certain activities;

i) controlled delivery;

j) obtaining traffic and location data processed by providers of public electronic communications networks or providers of electronic communications services intended for the public. (…)"

Code of Criminal Procedure - Article 139 Technical Surveillance

(…)

- (2) Technical surveillance may be ordered in cases of offenses against national security as provided for by the Criminal Code and special laws, as well as in cases of drug trafficking, offenses against the regulations governing doping substances, the conduct of illegal operations involving precursors or other products likely to have psychoactive effects, offenses involving non-compliance with regulations governing weapons, ammunition, nuclear materials, explosive substances, and restricted explosive precursors; trafficking in and exploitation of vulnerable persons; acts of terrorism; money laundering; counterfeiting of currency, stamps, or other securities; and counterfeiting of electronic payment instruments*), in the case of offenses committed through computer systems or electronic means of communication, property offenses, blackmail, rape, unlawful deprivation of liberty, tax evasion, in the case of corruption offenses and offenses assimilated to corruption offenses, crimes against the financial interests of the European Union, or in the case of other crimes for which the law provides for a prison sentence of 5 years or more. (…)"

Code of Criminal Procedure - Article 146^1 Obtaining data on a person's financial transactions

" (1) The collection of data regarding financial transactions may be ordered by the judge for rights and freedoms at the court that would have jurisdiction to hear the case in the first instance or by the court of the same level in whose jurisdiction the prosecutor's office is located from which the prosecutor who drafted the proposal is a member, regarding the financial transactions of the perpetrator, suspect, defendant, or

any person suspected of conducting such transactions with the perpetrator, suspect, or defendant, if:

a) there is reasonable suspicion regarding the preparation or commission of a crime;

b) the measure is necessary and proportionate to the restriction of fundamental rights and freedoms, given the particularities of the case, the importance of the information or evidence to be obtained, or the seriousness of the offense;

c) the evidence could not be obtained by other means, or obtaining it would entail particular difficulties that would prejudice the investigation, or there is a danger to the safety of persons or valuable property. (…)"

Code of Criminal Procedure - Article 147 Seizure, Handover, and Search of Postal Items

"(1) The seizure, handover, and search of postal items may be ordered by the judge for civil and administrative matters at the court to which has jurisdiction to hear the case in the first instance, or by the court of the corresponding level in whose jurisdiction the prosecutor's office is located to which the prosecutor who drafted the proposal belongs, with respect to letters, postal items, or objects sent or received by the perpetrator, suspect, defendant, or by any person suspected of receiving or sending such items by any means from the perpetrator, suspect, or defendant, or items intended for them, if:

a) there is reasonable suspicion regarding the preparation or commission of a crime;

b) the measure is necessary and proportionate to the restriction of fundamental rights and freedoms, given the particularities of the case, the importance of the information or evidence to be obtained, or the seriousness of the offense;

c) the evidence could not be obtained by other means, or obtaining it would entail particular difficulties that would prejudice the investigation, or there is a danger to the safety of persons or valuable property. (…)"

Code of Criminal Procedure - Article 148 Use of Undercover or Open Investigators and Informants

" (1) Authorization to use undercover investigators may be granted by the prosecutor supervising or conducting the criminal investigation for a period not exceeding 60 days, if:

a) there is reasonable suspicion regarding the preparation or commission of a crime against national security as provided for by the Criminal Code and other special laws, as well as in the case of drug trafficking offenses, offenses against the regulations governing doping substances, the conduct of illegal operations involving precursors or other products likely to have psychoactive effects, offenses involving non-compliance with regulations governing weapons, ammunition, nuclear materials, explosive materials, and restricted explosive precursors, trafficking and exploitation of vulnerable persons, acts of terrorism or similar acts, terrorist financing, money laundering, counterfeiting of currency, stamps, or other securities, counterfeiting of electronic payment instruments*), in the case of offenses committed through computer systems or electronic means of communication, extortion, unlawful deprivation of liberty, tax evasion, in the case of corruption offenses, offenses analogous to corruption offenses, offenses against the financial interests of the European Union, or in the case of other offenses for which the law provides for a prison sentence of 7 years or more, or where there is reasonable suspicion that a person is involved in criminal activities related to the crimes listed above;

b) the measure is necessary and proportionate to the restriction of fundamental rights and freedoms, given the particular circumstances of the case, the importance of the information or evidence to be obtained, or the seriousness of the offence;
c) the evidence or the location and identification of the perpetrator, suspect or defendant could not be obtained by other means, or obtaining it would involve significant difficulties that would prejudice the investigation, or there is a danger to the safety of persons or valuable property. (…)"
Code of Criminal Procedure - Article 150 Authorized Participation in Certain Activities
" (1) Authorized participation in certain activities under the conditions set forth in Art. 138(11) may be ordered by the prosecutor supervising or conducting the criminal investigation for a period of up to 60 days if:
a) there is reasonable suspicion regarding the preparation or commission of a drug trafficking offense, offenses against the regulations governing doping substances, or the conduct of illegal operations involving precursors or other products likely to have psychoactive effects, offenses involving non-compliance with regulations governing weapons, ammunition, nuclear materials, explosive substances, and restricted explosive precursors; trafficking in and exploitation of vulnerable persons; acts of terrorism or similar offenses; the financing of terrorism, money laundering, counterfeiting of currency, stamps, or other securities, an offense committed through computer systems or electronic means of communication, extortion, unlawful deprivation of liberty, tax evasion, in the case of corruption offenses, offenses equivalent to corruption offenses, and offenses against the financial interests of the European Union, or in the case of other offenses for which the law provides for a prison sentence of 7 years or more, or if there is reasonable suspicion that a person is involved in criminal activities related, pursuant to Article 43, to the offenses listed above;
(b) the measure is necessary and proportionate to the restriction of fundamental rights and freedoms, given the particular circumstances of the case, the importance of the information or evidence to be obtained, or the seriousness of the offense;
c) the evidence could not be obtained by other means, or obtaining it would entail particular difficulties that would prejudice the investigation or pose a danger to the safety of persons or valuable property. (…)"
Code of Criminal Procedure - Article 151 Controlled Delivery
" (1) A controlled delivery may be authorized, by order, by the prosecutor supervising or conducting the criminal investigation, at the request of the competent institutions or bodies, with or without the removal or total or partial substitution of the goods that are the subject of the delivery.
(2) Controlled delivery may be authorized only in the following cases:
a) if the detection or arrest of persons involved in the illegal transport of drugs, doping substances, weapons, stolen goods, restricted explosive materials and precursors, nuclear materials, other radioactive materials, sums of money, and other items resulting from illicit activities or items used for the purpose of committing crimes could not be achieved otherwise or would entail particular difficulties that would prejudice the investigation or pose a danger to the safety of persons or valuable property;
(b) if the detection or proof of offenses committed in connection with the delivery of illegal or suspicious shipments would otherwise be impossible or very difficult.

(2^1) A controlled delivery may be carried out within the country only if the prosecutor supervising or conducting the criminal investigation ensures that the authorities which, by law, have responsibilities regarding the verification or supervision of the entry, movement, or exit from the country of the goods in question:

a) maintain the confidentiality of the activities carried out;

b) ensure the continuous monitoring of the illegal or suspicious transport.

(3) Where a controlled delivery involves cross-border activities, it may be carried out only if the prosecutor supervising or conducting the criminal investigation takes measures to ensure that the authorities of the transit states:

a) agree to the entry of the illegal or suspicious shipment into their territory and its exit from the territory of the state;

b) ensure that the illegal or suspicious shipment is continuously monitored by the competent authorities;

c) guarantee that the prosecutor, police, or other competent state authorities are notified of the outcome of the criminal investigation against persons accused of offenses that were the subject of the special investigative method referred to in paragraph (1).

(4) The provisions of paragraph (3) shall not apply if an international treaty to which Romania is a party contains contrary provisions. (…)"

Code of Criminal Procedure - Article 152 Obtaining traffic and location data processed by providers of public electronic communications networks or providers of electronic communications services intended for the public

" (1) Criminal investigation authorities, with the prior authorization of the judge for rights and freedoms, may request traffic and location data processed by providers of public electronic communications networks or providers of electronic communications services intended for the public if all of the following conditions are met:

a) there is reasonable suspicion regarding the commission of an offense among those provided for in Article 139, para. (2), or an offense of unfair competition, escape, forgery of documents, offenses concerning non-compliance with the regime governing weapons, ammunition, nuclear materials, explosive substances, and restricted explosive precursors; an offense involving non-compliance with provisions regarding the importation of waste and residues into the country; an offense involving the organization and operation of gambling; or an offense involving the legal regime governing drug precursors, and offenses relating to operations involving products likely to have psychoactive effects similar to those caused by narcotic or psychotropic substances and products;

b) there are reasonable grounds to believe that the requested data constitutes evidence;

c) the evidence could not be obtained by other means, or obtaining it would involve significant difficulties that would prejudice the investigation, or there is a danger to the safety of persons or valuable property;

d) the measure is proportionate to the restriction of fundamental rights and freedoms, given the particularities of the case, the importance of the information or evidence to be obtained, or the seriousness of the offense. (…)"

Code of Criminal Procedure - Article 153 Obtaining Information Regarding a Person's Financial Situation

”(1) The prosecutor may request a credit institution or any other institution holding data regarding a person’s financial situation to disclose data regarding the existence and contents of a person’s accounts, if there are reasonable grounds to suspect that a crime has been committed and there are grounds to believe that the requested data constitutes evidence. (…)”

Question 12: Measures of protection for the victim

a. Please describe the measures taken to (**Article 19**):
   - ensure that victims have access to information relevant to their case and which is necessary for the protection of their health;
   - assist victims in their physical, psychological and social recovery;
   - provide for the right of victims to compensation from the perpetrators.

Law No. 211/2004 on Certain Measures to Ensure the Information, Support, and Protection of Victims of Crime

Article 1 This law regulates the measures for the information, support, and protection provided to victims of crime.

Article 3^2 The process of providing information, support, and protection to victims of crime comprises the following stages:

a) identification: establishing the status of victim of crime, within the meaning of this law;

b) referral—directing the victim to the Crime Victim Support Service, or to the departments and social service providers specified in Article 3^1;

c) initial information—providing the victim with general information regarding their rights and the services they are eligible to receive;

d) assessment of the victim’s situation by the Crime Victim Support Service, or the departments and social service providers specified in Article 3^1, to determine the support and protection measures available to the victim;

e) provision of support and protection services;

f) monitoring and evaluating the support and protection services.

Art. 7 - (1) Support and protection services provided to the victim of a crime or to members of the victim’s family shall be provided by the general directorates, free of charge, at the request of the victim or members of the victim’s family, and may also be provided by public social assistance services at the level of cities, municipalities, and communes, as well as by private social service providers, under the conditions set forth in Article 3^1.

(2) The request for the provision of support and protection services shall be addressed to the general directorate, but may also be addressed directly to a private or public social service provider, in which case the provider is required to inform, in writing, the general directorate within whose territorial jurisdiction the beneficiary of the respective service has their domicile or residence.

(3) Victims may also be referred, depending on their identified needs, to social, educational, or medical services, or to other services of general interest located nearby, provided in accordance with the law.

(4) The support and protection services provided to both victims of crimes and their family members may include:

a) information regarding the victim's rights;

b) psychological counselling, counselling regarding the risks of secondary and repeated victimization or of intimidation and retaliation;

c) counselling regarding financial and practical matters arising from the crime;

d) social integration/reintegration services;

f) information and counselling regarding the victim's role in criminal proceedings, including preparation for participation in the trial. These information and counselling services do not include the free legal assistance for victims of crimes provided for in Articles 14–20 or the legal assistance for the injured party provided for in Law No. 135/2010 on the Code of Criminal Procedure, as subsequently amended and supplemented;

g) referring the victim to other specialized services, when appropriate: social services, medical services, employment services, educational services, or other services of general interest provided in accordance with the law. (…)

b. Please describe the measures taken to inform victims of their rights, the services at their disposal, the follow-up given to their complaint, the charges, the general progress of the investigation or proceedings, and their role as well as the outcome of their cases (**Article 20, para. 1, letter (a) and para. 2**).

Law No. 211/2004 on Certain Measures to Ensure the Information, Support, and Protection of Victims of Crime
Article 4 (1) Judicial authorities are required to inform victims of crimes regarding:
a) the type of support victims may receive and from whom, including, where relevant, basic information regarding access to medical care, any type of specialized assistance, including psychological assistance and alternative housing;
b) the criminal investigation authority to which they may file a complaint;
c) the right to legal assistance and the institution to which they may turn to exercise this right;
d) the conditions and procedure for the provision of free legal assistance;
e) the procedural rights of the injured party and the civil party;
f) the conditions and procedure for benefiting from the provisions of Article 113 of the Code of Criminal Procedure, as well as the provisions of Law No. 682/2002 on witness protection, as amended;
g) the conditions and procedure for the granting of financial compensation by the state;

h) the right to be informed, in the event that the defendant is detained or sentenced to a custodial sentence, regarding his or her release in any form, in accordance with the Code of Criminal Procedure;

i) the right to seek the assistance of a mediator in cases permitted by law;

j) the judicial authority to which they may turn in the future to obtain information regarding the status of the case, as well as its contact details, if the victim intends to file a complaint;

k) if the victim has their residence or permanent home in another EU Member State, information regarding the possibility of filing a criminal complaint or a claim for financial compensation from the state within the territory of that state, as well as the fact that there is a possibility, under the legislation on international judicial cooperation, for the victim to be heard by the Romanian judicial authorities without being physically present in Romania.

(2) The information referred to in paragraph (1) shall be provided to the victim by the first judicial authority to which the victim appears, in language that is simple and accessible to the victim.

(3) The victim shall be provided with the information referred to in paragraph (1) in a language the victim understands. The victim shall be given, against signature, a form containing the information referred to in paragraph (1). If the victim is unable or refuses to sign, a record of this shall be made.

(4) If the victim is a Romanian citizen belonging to a national minority, the information provided for in paragraph (1) may be communicated to them in their native language.

(5) Compliance with the obligations set forth in paragraphs (1) through (3) shall be recorded in a report, which shall be filed with the institution to which the judicial body belongs.

(6) Upon first contact with the authorities, the victim may be accompanied by a person of their choice to facilitate communication with them.

(7) Upon filing a complaint pursuant to Article 289 of Law No. 135/2010 on the Code of Criminal Procedure, as amended and supplemented, the victim shall receive written confirmation thereof. The confirmation shall include the complaint's registration number, as well as details regarding the offense for which the complaint was filed.

(8) If the victim does not speak or understand Romanian, they may request to receive, at a later date, a translation of the written confirmation referred to in paragraph (7).

Article 4^1

(1) If the victim has not reported the offense to the criminal investigation authorities, the Crime Victim Support Service, as well as the departments and social service providers referred to in Article 3^1, shall inform the victim, upon first contact, of the rights set forth in Article 4.

(2) The information referred to in paragraph (1) shall be communicated to the victim in simple and accessible language. (…)

Code of Criminal Procedure, Article 81 Rights of the Victim

" (1) In criminal proceedings, the victim has the following rights:

a) the right to be informed of his or her rights;

b) the right to propose the admission of evidence by the judicial authorities, to raise objections, and to present arguments;

c) the right to make any other requests relating to the resolution of the criminal aspect of the case;

d) the right to be informed, within a reasonable time, of the status of the criminal investigation, upon her express request, provided that she provides an address within Romania, an email address, or an instant messaging address to which this information may be communicated;

e) the right to inspect the case file, in accordance with the law;

f) the right to be heard;

g) the right to ask questions of the defendant, witnesses, and experts;

g^1) the right to receive free interpretation services when the victim does not understand, cannot express themselves well, or cannot communicate in Romanian. In urgent cases, technical means of communication may be used if deemed necessary and if they do not impede the exercise of the victim's rights;

g^2) the right to be provided with a translation into a language they understand of any decision not to prosecute, when they do not understand Romanian;

h) the right to be assisted by a lawyer or represented;

i) the right to seek the assistance of a mediator, in cases permitted by law;

j) other rights provided by law.

(2) A person who has suffered physical, material, or moral harm as a result of a criminal act for which criminal proceedings are initiated ex officio and who does not wish to participate in the criminal proceedings must notify the judicial authority thereof, which, if it deems it necessary, may hear the person as a witness."

Code of Criminal Procedure, Article 93 Legal Assistance for the Victim, the Civil Party, and the Civilly Liable Party

" (1) During the criminal investigation, the attorney for the victim, the civil party, or the civilly liable party has the right to be notified, under the conditions set forth in Article 92, para. (2), to be present during the performance of any act of criminal investigation under the conditions of Article 92, the right to consult the case file, and to file motions and submit briefs. The provisions of Article 89, para. (1) shall apply mutatis mutandis.

(2) The attorney for the injured party, the civil party, or the party liable for civil damages has the right provided for in Article 92(8).

(3) During the trial, the attorney for the victim, the civil party, or the party liable for civil damages shall exercise the rights of the person represented, except for those that the person exercises personally, and the right to inspect the case file.

(4) Legal representation is mandatory when the injured party or the civil party is a person lacking legal capacity or having limited legal capacity.

(5) When the court determines that, for certain reasons, the injured party, the civil party, or the civilly liable party is unable to defend themselves, it shall order measures to be taken for the appointment of a court-appointed attorney."

c. Please also indicate which measures have been taken to enable the victim to be heard, to supply evidence and to choose the means of having his/her views, needs and concerns presented, directly or through an intermediary, and considered (**Article 20, para. 1, letter (b)**);

See point b.

d. What kind of support services are provided to victims so that their rights and interests are duly presented and taken into account? (**Article 20, para. 1, letter (c)**)

See point b.

e. Please describe the measures taken to provide the safety of the victims, their families and witnesses from intimidation and retaliation (**Article 20, para. 1, letter (d)**);

Code of Criminal Procedure, Article 113 Protection of the Victim and the Civil Party
" (1) When the conditions provided by law regarding the status of a threatened or vulnerable witness or for the protection of privacy or dignity are met, the criminal investigation authority may order, with respect to the victim or the civil party, the protective measures provided for in Article 124 - 130, which shall apply mutatis mutandis.
(2) The following are presumed to be vulnerable: child victims, victims who are in a relationship of dependency with the perpetrator, victims of terrorism, organized crime, human trafficking, violence in close relationships, sexual violence, or exploitation, victims of hate crimes, and victims affected by a crime due to prejudice or discrimination that may be related in particular to their personal characteristics, victims with disabilities, as well as victims who have suffered considerable harm as a result of the seriousness of the crime.
(3) If the victim or the civil party is in any of the situations provided for in paragraph (2), the criminal investigation authority shall inform them of the protective measures that may be taken, their content, and the possibility of waiving them. The victim's or civil party's waiver of protective measures shall be recorded in writing and signed by them, in the presence of their legal representative, if applicable
(4) The victim shall be re-examined only if this is strictly necessary for the conduct of the criminal proceedings.
(5) At the hearing, the victim may be accompanied, at their request, by their legal representative and by another person designated by the victim, unless the judicial authority decides otherwise with a reasoned decision.
(6) Whenever the judicial authority cannot determine the age of the victim and there are grounds to believe that the victim is a minor, the victim shall be presumed to be a minor."

f. Please specify under which conditions victims of the offences established according to the Convention have access to legal aid provided free of charge (**Article 20, para. 3**).

Law No. 211/2004 on certain measures to ensure the provision of information, support, and protection to victims of crime
Article 12 Non-governmental organizations may organize, independently or in cooperation with public authorities, services for the psychological counselling of crime victims and for providing other forms of assistance to crime victims. To this end, non-governmental organizations may receive, under the conditions provided by law, subsidies from the state budget.
Article 14 (1) Free legal aid shall be provided, upon request, to the following categories of victims:

a) persons against whom an attempt was made to commit the crimes of murder or aggravated murder, as provided for in Articles 188 and 189 of the Criminal Code, a crime of bodily injury, as provided for in Article 194 of the Criminal Code, an intentional crime resulting in bodily injury to the victim, or a crime of rape, sexual assault, sexual intercourse with a minor, or sexual corruption of minors, as provided for in Articles 218–221 of the Criminal Code;

b) the spouse, children, and dependents of persons who died as a result of the commission of the offenses of murder and aggravated murder, as provided for in Articles 188 and 189 of the Criminal Code, as well as intentional offenses that resulted in the death of the person.

(2) Free legal aid shall be granted to the victims referred to in paragraph (1) if the offense was committed on the territory of Romania or, if the offense was committed outside the territory of Romania, if the victim is a Romanian citizen or a foreign national legally residing in Romania and the criminal proceedings are conducted in Romania.

Article 15 - Free legal aid shall be granted, upon request, to victims of crimes other than those provided for in Article 14, para. (2), provided that the victim's monthly income per family member is no more than the national minimum gross base salary established for the year in which the victim filed the application for free legal aid.

Article 16 - (1) Free legal aid shall be granted only if the victim has filed a complaint with the criminal investigation authorities or the court within 60 days of the date the crime was committed.

(2) In the case of victims referred to in Article 14(1)(b), the 60-day period shall be calculated from the date on which the victim became aware of the commission of the offense.

(3) If the victim was physically or mentally unable to report the offense to the criminal investigation authorities, the 60-day period shall be calculated from the date on which the state of incapacity ceased.

(4) Victims under the age of 18 and those under legal incapacitation are not required to report the commission of the offense to the criminal investigation authorities or the court. The legal representative of the minor or of the person under legal incapacity may report the commission of the offense to the criminal investigation authorities.

g. Which legislative or other measures have been taken to ensure that victims of an offence established in accordance with the Convention in the territory of a Party other than the one where they reside may make a complaint before the competent authorities of their state of residence? (**Article 20, para. 4, Explanatory Report, para. 128**).

The Romanian legislation does not contain any specific provisions dedicated exclusively to the Medicrime Convention. Instead, it applies the general cross-border mechanisms of European judicial cooperation and domestic rules on victim protection to enable the filing of a criminal complaint in the country.

h. Please describe how your internal law allows for groups, foundations, associations or governmental or non-governmental organisations assisting and/or supporting victims to participate in legal proceedings (for example, as third parties) (**Article 20, para. 5**). Please specify under which conditions, if so required;

The internal law does not provide such possibility.

V. PREVENTION OF COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 13: Ensure quality and safety requirements of medical products, awareness raising and training

a. Which legislative or other measures have been taken to establish the quality, efficacy and safety requirements of medical products? (**Article 18 para. 1, Explanatory Report, para. 113**)

Focused strictly on the pillars of quality, efficacy and safety, Romania's legal and administrative framework applies separate mechanisms for medicines and medical devices, regulated by Law No. 95/2006 on health care reform and the ministerial orders implementing it.

b. Which legislative or other measures have been taken to ensure the safe distribution of medical products? (**Article 18 para. 2**)

Through rules of good pharmaceutical practice and good distribution practice established by orders of the Minister of Health, which impose strict standards regarding the storage, transport and handling of medicines for human use.
The identification and traceability of medical devices and in vitro diagnostic medical devices, other than those subject to performance studies, shall be carried out through the Unique Device Identification (UDI) system, by Government Emergency Ordinance.

c. Which measures have been taken to provide for (**Article 18 para. 3 letters a and c, Explanatory Report, para. 114**):
   - training of healthcare professionals, providers, law-enforcement (including police and customs authorities), as well as other relevant authorities and civil society?

The police authorities participate in training sessions organized by Europol.
In March 2026, OSMR and NAMMDR launched the national campaign “Falsified Medicines Can Kill!”, a broad public information and awareness initiative aimed at drawing public attention to the serious risks associated with the use of counterfeit medicines.

   - the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?

Administrative sanctions have been regulated (Law no. 95/2006 on health care reform).

d. Which policies or strategies have been implemented to promote or conduct awareness-raising campaigns targeted at the general public where the focus is directed especially towards the risks and realities of the counterfeiting of medical

products and similar crimes involving threats to public health? Please describe the material used for the campaign/programme and its dissemination. If possible, please provide an assessment of the impact of the campaign/programme. If there are currently plans for launching a (new) campaign or programme, please provide details (**Article 18, para. 3 letter b**);

The national campaign “Falsified Medicines Can Kill!”, a broad public information and awareness initiative aimed at drawing public attention to the serious risks associated with the use of counterfeit medicines.