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
Directorate General I – Human Rights and Rule of Law

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*

[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.

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 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;

Responsible for collecting the replies to the questionnaire was designated Medicines and Medical Devices Agency. The questionnaire was distributed to Customs Service of the Republic of Moldova and General Police Inspectorate of the Ministry of Internal Affairs. The Ministry of Justice was asked to contribute to responding to this questionnaire on a later stage.

- 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.
  - The Penal Code (No. 985 of 18.04.2002) - https://www.legis.md/cautare/getResults?doc_id=122429&lang=ro
  - The Criminal Procedure Code (No. 122 of 14.03.2003) - https://www.legis.md/cautare/getResults?doc_id=122065&lang=ro
  - The Contravention Code (No. 218 of 24.10.2008) - https://www.legis.md/cautare/getResults?doc_id=122879&lang=ro
  - Law No. 1409 of 17.12.1997 on medicines - https://www.legis.md/cautare/getResults?doc_id=115116&lang=ro
  - Law No. 102 of 09.06.2017 on medical devices - https://www.legis.md/cautare/getResults?doc_id=119271&lang=ro
  - *Law No. 1456 of 25.05.1993 on pharmaceutical activity - https://www.legis.md/cautare/getResults?doc_id=115108&lang=ro#*

III. GENERAL FRAMEWORK

Question 1: Definitions

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

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”?
The Penal Code (No. 985 of 18.04.2002) determines the object of the criminal offence without mentioning directly the term ”medical product”. It address the term ”product”, bearing in mind the definitions provided national organic laws (*Law No. 1409 of 17.12.1997 on medicines and Law No. 102 of 09.06.2017 on medical devices*) mentioned bellow.

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”?

   According to *Article 3, Law No. 1409 of 17.12.1997 on medicines* the term ”medicines (medicinal products)” is defined as ”substances or combination of substances authorized, in the prescribed manner, for manufacture, import, export and use, to treat, alleviate, prevent, diagnose a disease, an abnormal physical or mental condition or their symptoms in humans, or animal, as well as to restore, correct and modify their organic functions”
   The investigational medicinal product term is not mentioned expressly in the definition, but is considered included as per Article 2, para 2 of the same law that states: ”This law applies to all areas of activity of medicines: investigation, testing, approval, manufacture, application, use, import, export, storage, distribution, sale, control.”

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 medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product”?
According to *Article 3, Law No. 1409 of 17.12.1997 on medicines* the term ”active substance” is defined as ”biological” active substance, of natural, synthetic or biotechnological origin, used in the manufacture or preparation of medicinal products”. The definition of Active Pharmaceutical Ingredient (API) set out in*, MMDA order No. 24 of 04.04.2013 on the approval of the Guide on Good Manufacturing Practice (GMP) for human use* corresponds exactly to that one set out in **Article 4, letter (c).**

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”?
The definition of ”excipient” is foreseen in *Guideline on Excipients in the labelling and package leaflet of medicinal products for human use approved by MMDA order no.*

A07.PS-01.Rg04-309 of 28.12.2015 and is set as ”Any constituent of a medicinal product other than the active substance and the packaging material.”

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”?

   The definition of term ”medical devices” is set out in *Article 2, Law No. 102 of 09.06.2017 on medical devices* and represents ”any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper functioning, designated by the manufacturer to be used for human beings for the purpose of:
   a) diagnosis, preventing, monitoring, treating or alleviation a disease;
   b) diagnosis, preventing, supervision, treatment, alleviation or compensation for an injury or handicap;
   c) investigation, replacement or modification of the anatomy or of a physiological process;
   d) control of the conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but whose functioning can be assisted by such means;”

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”?

   According to *Article 2, Law No. 102 of 09.06.2017 on medical devices* the term ”accessory” is defined as ”any article which whilst not being a medical devices, is designated to be used together with a medical device to enable it to be used in accordance with the purpose intended by the manufacturer”

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”?

   The terms ”parts” and ”materials” are considered to correspond to ”other article” and ”material” mentioned in the definition of medical device, provided above.

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”?
Article 246[2] of The Penal Code (No. 985 of 18.04.2002) refers to accompanying documents, documents of origin, quality and compliance documents.

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;
   According to provisions of Article 18 of *Law No. 1409 of 17.12.1997 on medicines*, manufacturing facilities of medicinal products must comply with GMP. Thereof, section 1 of the *MMDA order No. 24 of 04.04.2013 on the approval of the Guide on Good Manufacturing Practice (GMP) for human use* states that ”manufacture” represents ”all operations related to the purchase and receipt of materials and products, production, packaging, repackaging, labeling, relabeling, quality control, release, storage, distribution of medicinal products or API, as well as related controls.”

   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;
   According to the definition set out in *Regulation on the conditions for placing on the market of medical devices,* approved under Government Decision No. 702 of 11.07.2018 ”manufacturer” of medical device is ”natural or legal person responsible for design, manufacture, packaging and labelling of a medical device for placing on the market under his own name, whether this operation is carried out by himself or by a third party on his behalf (responsible for placing on the market)”.
   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”?
   According to the *Regulation* mentioned above ”This Regulation applies to medical devices and their accessories (hereinafter - devices). For the purposes of this Regulation, accessories are considered to be medical devices per se”.

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”?
In the legislation of the Republic of Moldova, the term “counterfeit” is also used, which corresponds to that one set out in **Article 4 letter (j)** of the Convention, ie “a false representation as regards identity and/or source”.
The given term is found in the provisions of article 214[1] of The Penal Code, "Production or sale of counterfeit medicine."

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"?

According to article 58 of the Criminal Procedure Code (No. 122 of 14.03.2003), "Victim", is considered any natural or legal person to whom, through crime, moral, physical or material damages have been brought.

Thus, in the criminal-procedural legislation of the Republic of Moldova, the term "victim" is defined in general, for all types of crimes, but, in essence, it corresponds to the provisions of **Article 4 letter (k)** of the Convention.

According to article 387 of the Contravention Code ,,The victim is a natural person or a legal person to whom, by contravention, has been caused moral, physical or material damages.

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.

The criminal process is based on a series of principles that ensure the smooth running of the process, including the principle of equality before the law and authorities, provided by article 9 of Criminal Procedure Code. According to the rule in question, "*all are equal before the law, before the criminal prosecution and the court, regardless of sex, race, color, language, religion, political opinion or any other opinion, national or social origin, membership of a national minority, wealth, birth or any other institution*".

Therefore, the legislation of the Republic of Moldova prohibits any discrimination in criminal proceedings.

Likewise in the Contravention Code, article 6 is provided the principle of equality before the law. According to this article, "*persons who have committed contraventions are equal before the law and public authorities and are subject to criminal liability regardless of race, nationality, language, religion, sex, political affiliation, wealth, social origin or any other situation*."

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;

In the Contravention Code, para. (4) of article 77 "Illicit practice of medical and pharmaceutical activity" are presented sanctions for *improper storage of medicinal products, storage, use, advertising and marketing of medicines not authorized for use, of medicines with expired date, as well as those without the document and / or information attesting the quality and without the name and address of the manufacturer*, and at para. (6) for the *manufacturing, modification of the manufacturing formula, of the technological flow, labeling of medicines, of other pharmaceutical and parapharmaceutical products, as well as of the technical-normative documentation, by*

the companies manufacturing medicines, other pharmaceutical and parapharmaceutical products without the respective authorization.

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;
Currently there was not adopted a national strategy and/or Action Plan to combat counterfeiting of medical products, bearing in mind that according to the Convention, the term “counterfeit” corresponds to the term “false” without the connotations to intellectual property rights.

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.

In accordance with the provisions of the Parliament Decision No. 153 of 15.07.2011 for the approval of the National Security Strategy of the Republic of Moldova, point 4.5 "Improvement of demographic situation, population health and ensureance of pharmaceutical security", the Central Public Authorities will develop and implement the strategy and strategic plan on strengthening pharmaceutical security in the Republic of Moldova, with the aim of preventing the introduction on the pharmaceutical market of falsified medicines, of non-compliant quality; ensuring the safety of medicines by strengthening clinical research and pharmacovigilance; ensuring the proper storage of medicines in pharmaceutical companies; development of the national pharmaceutical industry and others.

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**);
There are no formal agreements between competent authorities. Any of the cases identified by a competent authority is communicated to other relevant authority on a case by case basis.

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**)
According to the provisions set out in *Order of the Ministry of Health No. 1400 of 09.12.2014 on the approval of the Rules of Good Distribution Practice of Medicines (GDP) for human use*, ” Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified”.

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)**);
  Any of the cases identified by a competent authority is communicated to other relevant authority on a case by case basis.

- 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)**);
  According to the provisions set out in the *Government Decision No. 777 of 13.08.1997 on improving the foreign trade regulatory mechanism* export, import and re-export of medical products is performed based on relevant authorization. Regulation on the authorization of the import-export of medicines, other pharmaceutical and parapharmaceutical products are set out in Medicines and Medical Devices Agency Order No. 1 of 16.01.2006.

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**);
Pharmaceutical activity GMP, GDP and GPP authorization unit and Quality Control Laboratory are units of Medicines and Medical Devices Agency, directly involved in exchange of information in respect of non compliant medicines (falsified, with quality defects). Information about training of the personnel of this units is provided under question 13, c.

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**).
Representative of the Republic of Moldova in the MEDICRIME Committee is nominated Mr. Dumitru Saghin, Deputy Director General, Medicines and Medical Devices Agency.

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.
The National Investigation Inspectorate of the General Police Inspectorate carries out the PANGEA XIII operation, which aims to monitor and counteract crimes in the field of medicine, counteract the import / illicit trade of medical equipment / products and monitor and verify compliance by economic agents and individuals of the provisions

approved by the Commission for Exceptional Situations of the Republic of Moldova and at the request of the Sub-Directorate for Global Security and Health of the ICPO INTERPOL

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.

   As stated above, the crime of counterfeiting medicines is provided in articel 214[1] of The Penal Code.

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

   According to criminal law, persons who have committed crimes intentionally are liable to criminal liability, but the law also provides criminal liability for some acts committed recklessly.

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;

   The contravention legislation of the Republic of Moldova establishes the punishment for the act of "producing medicines under illegal conditions, without the respective authorization of the Ministry of Health", this being provided by article 77 of the Contravention Code.

   „**Article 77**. Illegal practice of medical and pharmaceutical activity

   (1) The practice as a profession of medical and pharmaceutical activity by a person who does not have the appropriate medical and pharmaceutical studies shall be sanctioned with a fine from 12 to 42 conventional units.

   (2) The practice by the person authorized to carry out pharmaceutical activities of some types of activity not indicated in the license shall be sanctioned with a fine from 12 to 30 conventional units applied to the natural person, with a fine from 24 to 42 conventional units applied to person in charge, with a fine from 30 to 60 conventional units applied to the legal person.

   (3) Carrying out the pharmaceutical activity in unauthorized places shall be sanctioned with a fine from 12 to 30 conventional units applied to the natural person, with a fine from 24 to 42 conventional units applied to the person in charge, with a fine from 30 to 60 conventional units applied to the legal person.

   (4) Improper storage of medicines, the storage, use, advertising and marketing of medicines not authorized for use, of medicines with expired date, as well as those without the document and / or information attesting the quality and without the name and address of the manufacturer, shall be sanctioned with a fine from 30 to 60 conventional units applied to the natural person, with a fine from 70 to 120 conventional units applied to the person in charge, with a fine from 100 to 150 conventional units applied to the legal person.

   (5) Violation of the rules for prescribing and dispensing medicines is punishable by a fine of 12 to 30 conventional units.

   (6) Manufacturing, modification of the manufacturing formula, of the technological flow, labeling of medicines, of other pharmaceutical and parapharmaceutical products, as well as of the technical-normative documentation, by companies manufacturing medicines, other pharmaceutical and parapharmaceutical products without the

respective authorization shall be sanctioned with a fine from 30 to 60 conventional units applied to the legal person.
(7) The practice of the pharmaceutical activity without the use of the informational system for recording the circulation of medicines, the use of this system in violation of the established requirements shall be sanctioned with a fine from 60 to 90 conventional units applied to the person in charge, with a fine from 72 to 102 conventional units applied to the legal person
(8) Practice of traditional medicine without special authorization, issued in the manner established by law, is sanctioned with a fine from 24 to 30 conventional units with or without deprivation of the right to carry out a certain activity from 3 months to one year."

Article 5 – Manufacturing of counterfeits

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.*

The provisions of article 5 ”Manufacturing of counterfeits” of the Convention are found in article 214[1] of The Penal Code, "Production or sale of counterfeit medicine", in the standard version that is manifested by the manufacture or sale of counterfeit medicines, including the aggravating variant, provided in para. (2) of this article, which establishes the punishment for recklessly causing serious or moderate injury to health or death of the person as a result of the crime.

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

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.*

The provisions of articles 6 and 8 of the Convention are reflected in the text of article 216 of The Penal Code ” Production, transportation, storage,

marketing, supply of products (goods) by onerous title or free of charge, provision of services dangerous to the life and health of consumers."

Article 7 – Falsification of documents

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*

Considering the provisions of article 7 of the Convention, the actions of falsification of documents described above are reflected in the text of article 361 of the Penal Code of the Republic of Moldova "Manufacture, possession, sale or use of official documents, printed materials, stamps or false seals".

Article 8 – Similar crimes involving threats to public health

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

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.

The terms of ”aiding or abetting” in the legislation of the Republic of Moldova are provided by article 42 of the Penal Code "Participants". According to paragraph (5) of this article, “Accomplice is the person who contributed to the commission of the crime through advice, guidance, information, provision of means or tools or removal of obstacles, as well as the person who previously promised to favor the offender, conceal the means or instruments of committing the crime, its traces or the objects acquired by criminal means or the person who promised in advance that he will procure or sell such objects. "

The term of ”attempt” is provided in article 27 of the Penal Code "Attempted crime".

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**).

In article 11 of the Penal Code of the Republic of Moldova "Application of criminal law in space" foresees jurisdiction over all offenses provided in this code, including all cases stipulated in Article 10 "Jurisdiction" of the Convention.

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.

The legislation of the Republic of Moldova stipulates that the legal person is also liable for illegal acts. Also, for the offense provided in article 214^1 of the Penal Code ”Production or sale of counterfeit medicine", the legal person is liable to criminal liability, and the sanction applied being harsher. Respectively, for committing the crime provided by para. (1) article 214^1 the legal person is imposed a penalty in the form of a fine in the amount of 4000 to 6000 conventional units with (or without) deprivation of the right to exercise a certain activity for a period of up to 3 years. For committing the deed provided in para. (2) article 214^1, the legal person is punished in the form of a fine in the amount of 4000 to 6000 conventional units with deprivation of the right to exercise a certain activity for a period of up to 5 years or with the liquidation of the enterprise.

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**);

   The criminal sanctions are provided in the Penal Code, as follows:

   Article 214^1. Production or sale of counterfeit medicine
   (1) The production or marketing of counterfeit medicinal products shall be punished by a fine in the amount of 1350 to 2350 conventional units with (or without) deprivation of

the right to hold certain positions or to exercise a certain activity for a period of up to 3 years, with a fine, applied to the legal person, in the amount of 4000 to 6000 conventional units with (or without) the deprivation of the right to exercise a certain activity for a period of up to 3 years.
(2) The same actions if they caused recklessly serious or average damage to the health or the death of the person shall be punished with imprisonment of up to 5 years, with a fine, applied to the legal person, in the amount of 4000 to 6000 conventional units with deprivation of the right to to exercise a certain activity for a period of up to 5 years or with the liquidation of the enterprise.

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**).

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**).

The aggravating circumstances, which are provided for the establishment of the punishment, are regulated in article 77 of the Penal Code and are taken into account when individualizing the punishment for all offenses provided by the Penal Code of the Republic of Moldova.

In article 214[1] of the Penal Code, “Production or sale of counterfeit medicines”, the aggravated variant, provided in para. (2) of this article, involves recklessly causing serious or moderate injury to health or death of the person as a result of committing this act.

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**).

In article 276 of the Criminal Procedure Code, the conditions when the criminal investigation is initiated based on the victim's complaint are expressly stipulated. In the case of offenses related to the production or sale of counterfeit medicines, the criminal investigation will be initiated if the criminal investigation body directly detects or is notified about the commission or preparation for the commission of such an offense.

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 the legislation of the Republic of Moldova, there are no units or services specifically responsible for criminal investigations in the field of MEDICRIME Convention. Criminal prosecution in the case of crimes related to the production or sale of counterfeit drugs is the responsibility of the criminal investigation body of the Ministry of Internal Affairs.

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**).
In order to discover serious, very serious and exceptionally serious crimes, special investigative measures may be carried out, according to article 132^2 of the Criminal Procedure Code.
Thus, due to the fact that the offense of counterfeiting medicinal product, provided in article 214^1 of the Penal Code, is attributed to the category of less serious crimes, upon its investigation, no special investigative measures can be carried out.

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.

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**).

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)**);

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)**)

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)**);

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**).

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**).

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 rights of the victim are stipulated in article 58 of the Criminal Procedure Code "Victim", where the measures indicated in article 20 of the Convention are provided.

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**)

The aim of state system of drug quality assurance is to ensure the market with qualitative, effective and safe medicinal products. The Medicines and Medical Devices Agency has to ensure the efficiency and safety of medicines that have passed the control, their compliance with quality standards, the fulfilment, in the process of development and manufacturing of medicines, the requirements that ensure their compliance with those standards. According to the *Order of the Ministry of Health No. 521 of 01.06.2012 on state quality control of medicines "medicines manufactured in the Republic of Moldova, as well as imported ones authorized by the Medicines and Medical Devices Agency, medicines received as humanitarian aid (hereinafter medicines) and raw material used in the preparation of medicines in pharmacies are subject to state quality control.".* The state quality control is performed by Quality Control Laboratory of Medicines and Medical Devices Agency.

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

Article 20[1], para 1 of Law No. 1456 of 25.05.1993 on pharmaceutical activity states that "medicines, other pharmaceutical and parapharmaceutical products are distributed through wholesale and retail distribution networks." For wholesale distribution, the compliance with Good Distribution Practice GDP is required as per *Order of Ministry of Health No. 1400 of 09.12.2014 on the approval of the Rules of Good Distribution Practice of medicinal products (GDP) for human use.*

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 MMDA employees receive training based on the annual training plan, which includes trainings, seminars and meetings organized by international bodies such as: World Health Organization (WHO), Pharmaceutical

Inspectorate Co-operation Scheme (PIC/s), European Directorate for the Quality of Medicines & HealthCare (EDQM) where are addressed issues of preventing falsified medicinal products from entering the legal supply chain.

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

  As a measure to prevent supplying of counterfeit medical products on pharmaceutical market, all of the medicines manufactured in Republic of Moldova and imported ones are subject to state quality control, performed by Quality Control Laboratory of Medicines and Medical Devices Agency. Furthermore, based on collaboration with WHO and EDQM are received data through Rapid Alert System.

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**);