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

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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.*
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> 2. *States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.*
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> 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"?

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"?

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"?

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

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

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"?

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"?

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"?

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"?

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"?

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"?

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”?

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”?

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.

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;

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;

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**);

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**)

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)**);

    - 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)**);

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**);

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**).

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.

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.

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

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

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

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

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.*

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**).

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.

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**);

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**).

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**).

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**).

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**).

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;

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**)

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

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

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**);