**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.*
>
> 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"?

*Act defining medicinal products in Croatia is Medicinal Products Act (Official Gazette, no. 76/13, 90/14 and 100/18), whereas medical devices are defined by Medical Devices Act (Official Gazette, no. 76/13) Separate legislation is in place for medicinal products for veterinary use, i.e. these are not encompassed by the legislation for human medicinal products indicated above.*

*Article 3 of Medicinal Products Act:*
*1. Medicinal product shall mean:*
*- any substance or combination of substances presented as having properties for curing or preventing disease in human beings, or*
*- any substance or combination of substances which may be used 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 make a medical diagnosis,*

*Article 3 of Medical Devices Act:*
*1. 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

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

*— diagnosis, prevention, monitoring, treatment or alleviation of disease,*
*— diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,*
*— investigation, replacement or modification of the anatomy or of a physiological process,*
*— 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;*

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"?

*Yes, the understanding of "medicinal product" under Medicinal Products Act corresponds to that set out in Article 4, letter (b) with the exception of the last paragraph, since the investigational product is defined separately, by Article 29 of the same Act:*

*<u>Article 29 of Medicinal Products Act:</u>*
*Investigational medicinal product shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already authorised for marketing but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form,*

*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"?

*Active substance is defined by Medicinal Products Act as follows:*

*<u>Article 3 of Medicinal Products Act:</u>*
*3. Active substance shall mean any substance or combination of substances used in the manufacture of a medicinal product and becoming an active ingredient of the medicinal product, intended to furnish pharmacological, immunological or metabolic activity with a view to restoring, correcting or modifying physiological functions or making a medical diagnosis,*

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”?

*Excipient is defined by Medicinal Products Act as follows:*

*Article 3 of Medicinal Products Act:*
*4. Excipient shall mean any constituent of a medicinal product other than the active substance or 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”?

*Medical device is defined by Medical Devices Act as follows:*

*Article 3 of Medical Devices Act:*
*1. ‘Medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*
*— diagnosis, prevention, monitoring, treatment or alleviation of disease,*
*— diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,*
*— investigation, replacement or modification of the anatomy or of a physiological process,*
*— 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"?

*Accessory is defined by Medical Devices Act as follows:*

*Article 3 of Medical Devices Act:*
*2. 'Accessory' means an article which whilst not being a medical device is intended 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 device intended by the manufacturer of the 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"?

*There are no separate definition of "parts" and "materials" in Medical Devices Act.*

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"?

*There is no separate definition of "document" in Medical Devices Act.*

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"?

*Article 3 of Medical Devices Act defines a manufacturer as a:*
*natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.*

*Manufacturing of an accessory is not explicitly defined in Medical Devices Act.*

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"?

*Medicinal Products Act defines falsified medicinal product as follows:*

> *Article 3 of Medicinal Products Act:*
> *49. Falsified medicinal product shall mean any medicinal product which is deliberately and fraudulently mislabelled with respect to:*
> *a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*
> *b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder, or*
> *c) its history, including the records and documents relating to the distribution channels used.*
> *This definition shall not apply to unintentional quality defects and to infringements of intellectual property rights,*

*There is no definition of falsified medical device in Medical Devices Act.*

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"?

*The definition of the victim under the Croatian internal law corresponds to that given in the Article 4 letter (k) of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter "the MEDICRIME Convention"). We point to the Article 87 paragraph 25 of the Criminal Code (Official Gazette 125/11, 144/12, 56/15, 61/15, 101/17, 118/18, 126/19; hereinafter reffered to as CC) as well to the Article 202 paragraph 11 of the Criminal Procedure Act (Official Gazette 152/08, 76/09, 80/11, 121/11, 91/12, 143/12, 56/13, 145/13, 152/14, 70/17, 126/19; hereinafter reffered to as CPA).*

## 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.

*Discrimination on the grounds such as the ones mentioned in the indicative list in Article 2 of the MEDICRIME Convention is prohibited in the Croatian internal law. We point to the Article 6 paragraph 1 of the CPA.*

### 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;

*The Criminal Code (Official Gazette nos. 125/11, 144/12, 56/15, 61/15, 101/17, 118/18, 126/19, hereinafter: the CC) prescribes criminal offence of Counterfeiting of Medicines or Medical Products in Article 185 of the CC.*
*As far it concerns criminal proceedings regarding the criminal offences brought by the MEDICRIME Convention, such criminal proceedings are instituted and conducted on the basis of the CPA. We point to the Article 1 of the CPA, according to which this Act establishes the rules which guarantee that an innocent person shall not be convicted and that a punishment or some other measure shall be imposed on the person who commits a criminal offence, under the conditions stipulated by law and in lawful proceedings before the competent court. Furthermore, it prescribes that criminal prosecution and criminal proceedings may be conducted and concluded only according to the rules and under the conditions laid down by law.*

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;

*There is no national strategy currently in place.*

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.

*Market surveillance through monitoring the quality and safety of the use of medical products in the market including falsified medicines is included in Strategic plan of Agency for Medicinal Products and Medical Devices (HALMED).*

### 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**);

*SPOC network in the country is set and includes contacts from Police, Customs, Ministry of Health, Agency for Medicinal Products and Medical Devices and State Attorney Office. National SPOC receives information on national and international level and disseminates it through the Network.*

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**)

*Even though the cooperation between the competent authorities and the commercial and industrial sectors is not set formal, information about falsified medicinal products is regularly exchanged.*

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)**);

*A Memorandum of understanding between HALMED and Ministry of Internal Affairs is in the process of signing.*

    - 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)**);

*A Memorandum of understanding between HALMED and Ministry of Internal Affairs is in the process of signing.*

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 contact point appointed in Croatia: Ljubica Hodak Burić, M. Eng. Bioproc., univ. spec. techn. aliment., GMP Inspector Expert*
*Deputy: Rajka Truban Žulj, MPharm, Deputy Head for Operations*
*Agency for Medicinal Products and Medical Devices (HALMED)*

*National contact point and deputy contact point are members of Heads of Medicines Working group of Enforcement Officers. Deputy contact point is a member of Council of Europe Committee of experts on minimising public health risks posed by counterfeiting of medical products and similar crimes, CD-P-PH/CMED.*
*They have undergone a number of educations and workshops related to falsified medicines, including the following:*

- *WHO training course on building global capacity for surveillance and monitoring of SSFFC medicines, 5-7 September 2012, Manila, Philippines*
- *EDQM regional training: Working across disciplines and borders-Best Practices to Combat counterfeiting of medical products/Similar crimes and to protect public health*
- *INTERPOL Single Point of Contact Conference, 10-11 March 2015, France*
- *EDQM Expert workshop: Communication about the risks posed by counterfeit medical products and similar crimes, 29 November 2011*.

### 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 contact point appointed in Croatia: Ljubica Hodak Burić, M. Eng. Bioproc., univ. spec. techn. aliment., GMP Inspector Expert*
*Deputy: Rajka Truban Žulj, MPharm, Deputy Head for Operations*
*Agency for Medicinal Products and Medical Devices (HALMED)*

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.

*Currently there are no such programmes developed in Croatia.*

## 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.

*Intentional conducts referred to in Articles 5, 6, 7, 8 b and 9) of the MEDICIRIME Convention are considered criminal offenses in Croatian law. These conducts are criminalized by the Article 185 of the CC prescribing the criminal offence of Counterfeiting of Medicines or Medical Products.*

*Counterfeiting of Medicines or Medical Products*

*Article 185 of the CC*

*(1) Whoever manufactures a counterfeit medical, active substance, excipient, medical product, its components or paraphernalia, or modifies a genuine medicine, active substance, excipient or medical product, its components or paraphernalia shall be punished by imprisonment for from six months to five years.*

*(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified a medicine , active substance, excipient, medical product, its components or paraphernalia.*

*(3) Whoever counterfeits or modifies the original inner or outer package of a medicine or medical product, summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years.*

*(4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicine or medical product, the summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicines and medical products.*

*(5) Whoever commits the offence referred to in paragraph 1, 2, 3 or 4 of this Article by abusing the trust he or she enjoys as an expert, manufacturer or supplier, or commits it through the media suitable for mass distribution, such as information systems, including the internet, shall be punished by imprisonment from one and eight years.*

*(6) The attempt of the criminal offence referred to in paragraph 3 or 4 of this Article shall be punishable.*

*(7) Products and means of production shall be confiscated.*

*Aiding and abetting the commission of criminal offences established in accordance with the MEDICIRME Convention shall be punished on the basis of general institutes prescribed by Articles 37 and 38 of the CC. These provisions are located in the General part of the CC and, according to Article 6 of the CC, they apply to all criminal offences prescribed by the CC.*

*Solicitation*

*Article 37 of the CC*

*(1) Whoever intentionally incites another to commit a criminal offence shall be punished as if he or she himself or herself has committed it.*

*(2) Whoever intentionally incites another to commit a criminal offence for which an attempt is punishable, but the solicited offence has never even been attempted, shall incur the penalty provided for an attempt to commit such an offence.*

*(3) In the case of an inappropriate attempt of solicitation, the solicitor may receive remittance of punishment.*

*Aiding and Abetting*

*Article 38 of the CC*

*Punishment may be equal or mitigated to whoever intentionally aids and abets another in the commission of a criminal offence.*
*The attempt to commit criminal offences established in the accordance with the MEDICIRIME Convention shall be punished, as follows:*

*The attempt to commit criminal offences referred to in Article 185 paragraphs 1, 2 and 5 of the CC is punishable according to Article 34 of the CC. This provision prescribes the conditions for the attempt to commit a criminal offence to be punishable and it is located in the General part of the CC and, according to Article 6 of the CC, it applies to all criminal offences prescribed by the CC.*

*Attempt*

*Article 34 of the CC*

*(1) Whoever, with the intent to commit a criminal offence, performs an act which is spatially and temporally proximate to the realisation of the material elements of the criminal offence shall be punished for the attempt, provided that a sentence of imprisonment of five years or a more severe punishment may be imposed or that the law expressly provides for the punishment of an attempt.*

*(2) The punishment of a perpetrator of an attempt may be mitigated.*

*(3) If the perpetrator due to gross ignorance attempts to commit a criminal offence by unsuitable means or towards an unsuitable object the court may remit the punishment.*

*The attempt to commit criminal offences referred to in Article 185 paragraphs 3 and 4 of the CC (for which the maximum sentence prescribed is three years of imprisonment) is punishable on the basis of Article 185 paragraph 6 of the CC.*

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

*Yes, criminal offence referred to in Article 185 of the CC can be committed only intentionally.*

*Article 27 paragraph 1 of the CC prescribes that the intentional conduct shall be punishable. Negligent conduct is punishable only when law expressly provides for criminal liability.*

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;

*Preparation and Production of Harmful Products for the Treatment of People*

*Article 186 of the CC*

*(1) Whoever prepares or produces as a medicine, homoeopathic product or medical product for the purpose of sale or otherwise putting into circulation substances or products that are harmful to people's health and thereby endangers the health of another person shall be punished by imprisonment not exceeding three years.*

*(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures, processes, distributes or puts in the circulation infected blood or other tissue or makes means of treatment therefrom.*

*(3) Whoever commits the criminal offence referred to in paragraph 1 or 2 of this Article by negligence shall be punished by imprisonment not exceeding one year.*

*(4) Products and means of production shall be confiscated.*

*Careless Conduct in Preparing and Dispensing Medicine*

*Article 187 of the CC*

*(1) A pharmacist or another person authorised to prepare or dispense medicine for use in medicine, who prepares a medicinal product contrary to the of the rules of his or her profession or dispenses a wrong medicine and thereby endangers the health of another person shall be punished by imprisonment not exceeding three years.*

*(2) If the criminal offence referred to in paragraph 1 of this Article was committed by negligence, the perpetrator shall be punished by imprisonment not exceeding 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.*

***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**).

*Jurisdiction rules are prescribed by the following Articles of the CC:*

*Criminal Offences Committed in the Territory of the Republic of Croatia*

*Article 10 of the CC*

*The criminal legislation of the Republic of Croatia shall apply to anyone who commits a criminal offence in its territory.*

*Criminal Offences Committed Aboard a Croatian Vessel or Aircraft*

*Article 11 of the CC*

*The criminal legislation of the Republic of Croatia shall also apply to anyone who commits a criminal offence aboard a Croatian vessel or aircraft, regardless of the location of the vessel or the aircraft at the time the criminal offence was committed.*

*Particularities Concerning the Institution of Criminal Proceedings for Criminal Offences Committed within the Territory of the Republic of Croatia, Aboard its Vessel or Aircraft*

*Article 12 of the CC*

*Where, in the case of application of the criminal legislation of the Republic of Croatia pursuant to the provisions of Articles 10 and 11 of this Code, criminal proceedings in a foreign country have ended with a judgment having the force of res judicata, criminal proceedings in the Republic of Croatia shall be instituted upon authorisation from the Attorney General.*

*Criminal Offences Committed Abroad against a Domestic Legal Interest*

*Article 13 of the CC*

*The criminal legislation of the Republic of Croatia shall apply to anyone who, outside its territory, commits:*
*1. a criminal offence against the Republic of Croatia referred to in Title XXXII of this Code,*
*2. the criminal offence of counterfeiting money, securities and value signs of the Republic of Croatia referred to in Articles 274, 275 and 276 of this Code,*
*3. a criminal offence against a Croatian state official or a civil servant relating to his or her office,*
*4. a criminal offence of false testimony referred to in Article 305 of this Code if the false testimony was given in proceedings before Croatian competent authorities,*
*5. a criminal offences against the right to vote referred to in Title XXXI of this Code,*
*6. a criminal offence referred to in Articles 193, 194, 196, 197 and 198 of this Code when committed in the ecological and fisheries protection zone, epicontinental belt or in open sea.*

*Criminal Offences Committed Outside the Territory of the Republic of Croatia by its Nationals*

*Article 14 of the CC*

*(1) The criminal legislation of the Republic of Croatia shall be applied to its national or a person who has his or her permanent residence in its territory who outside the territory of the Republic of Croatia commits a criminal offence other than those specified in the provisions of Articles 13 and 16 of this Code, if the act is a criminal offence at the locality of its commission.*

*(2) The provision of paragraph 1 of this Article shall also apply to cases where the perpetrator acquires Croatian nationality after having committed the criminal offence.*

*(3) In cases referred to in paragraphs 1 and 2 of this Article, with respect to criminal offences established in Article 115, paragraphs 3 and 4, and Articles 116, 153, 154, 158, 159, 161, 162, 163, 164, 166 and 169 of this Code and other criminal offences for which this is provided by international treaties to which the Republic of Croatia is a party, the criminal legislation of the Republic of Croatia shall apply even if the act is not a criminal offence at the locality of its commission.*

*(4) Where a Croatian national participates in peacekeeping operations or other international activities outside of the territory of the Republic of Croatia and commits in such operations or activities a criminal offence, the application of the legislation of the Republic of Croatia shall be governed by the provisions of this Code, unless otherwise provided by an international treaty to which the Republic of Croatia is a party.*

*Criminal Offences Committed Outside the Territory of the Republic of Croatia against its Nationals*

*Article 15 of the CC*

*(1) The criminal legislation of the Republic of Croatia shall apply to an alien who outside the territory of the Republic of Croatia perpetrates a criminal offence other than those specified in the provisions of Articles 13 and 16 of this Code against a Croatian national, a person with a permanent residence in the Republic of Croatia or a legal person registered in the Republic of Croatia, if the act is also a criminal offence at the locality of its commission.*

*(2) In the case referred to in paragraph 1 of this Article, the court may not impose a penalty more severe that the one prescribed by the law of the country in which the criminal offence was committed.*

*Criminal Offences Committed Abroad against Internationally Protected Legal Interests*

*Article 16 of the CC*

*The criminal legislation of the Republic of Croatia shall apply to anyone who outside its territory commits any of the criminal offences referred to in Articles 88, 90, 91, 97, 104, 105 and 106 of this Code or a criminal offence which the Republic of Croatia is required to punish under an international treaty even though committed abroad.*

*Other Criminal Offences Committed Abroad*

*Article 17 of the CC*

*(1) The criminal legislation of the Republic of Croatia shall apply to an alien who outside its territory commits a criminal offence for which under the Croatian law a punishment of five years of imprisonment or a more severe penalty may be imposed, where this does not concern the cases referred to in Articles 13 through 16 of this Code, if the act is a criminal offence at the locality of its commission and if the extradition of the perpetrator is permitted under the law or an international treaty but has not been made.*

*(2) With respect to the case referred to in paragraph 1 of this Article, the court may not pronounce a sentence that is more severe than the one provided for by the law of the country in which the criminal offence was committed.*

*Particularities Concerning the Institution of Criminal Proceedings for Criminal Offences Committed Abroad*

*Article 18 of the CC*

*(1) Where, in the case of application of the criminal legislation of the Republic of Croatia pursuant to provisions of Article 13 of this Code, criminal proceedings have ended in a foreign country with a judgment having the force of res judicata, the Attorney General may desist from criminal prosecution.*

*(2) In cases referred to in Article 14 of this Code, criminal proceedings for the purpose of applying the criminal legislation of the Republic of Croatia shall not be instituted:*
*1. if the res judicata sentence has been carried out or is in the process of being carried out or can no longer be carried out under the law of the country in which the person was convicted,*
*2. if the perpetrator has been acquitted in a foreign country by a judgment having the force of res judicata or if he or she has been granted pardon under the law of the country in which he or she committed the criminal offence,*
*3. if the statute of limitations for criminal prosecution has expired.*

*(3) In cases referred to in Article 14 paragraphs 1 and 2 of this Code, criminal proceedings for the purpose of applying criminal legislation of the Republic of Croatia shall not be instituted if under the law of the country in which the criminal offence has been committed, such offence is prosecuted on the basis of a complaint or private action, and such a complaint has not been filed or an action has not been brought.*

*(4) In cases referred to in Article 14 paragraph 3 of this Code, criminal proceedings for the purpose of applying criminal legislation of the Republic of Croatia shall be instituted if under the law of the country in which the criminal offence has been committed, such offence is prosecuted on the basis of a complaint or private action, and such a complaint has not been filed or an action has not been brought.*

*(5) In cases referred to in Articles 15 and 17 of this Code, criminal proceedings for the purpose of applying criminal legislation of the Republic of Croatia shall not be instituted:*
*1. if the res judicata sentence has been carried out or is in the process of being carried out or can no longer be carried out under the law of the country in which the person was convicted,*
*2. if the perpetrator has been acquitted in a foreign country by a judgment having the force of res judicata or if he or she has been granted pardon under the law of the country in which he or she committed the criminal offence,*
*3. if under the law of the country in which the criminal offence has been committed, such offence is prosecuted on the basis of a complaint or private action, and such a complaint has not been filed or an action has not been brought, or the statute of limitations for criminal prosecution has expired.*

*(6) In the case referred to in Article 16 of this Code, criminal proceedings for the purpose of applying criminal legislation of the Republic of Croatia may be instituted provided that criminal prosecution has not been initiated before the International*

*Criminal Court or a court of another country or that due process before a court of the country in which the criminal offence was committed, a court of the country of which the perpetrator is a national or another court with jurisdiction over the case cannot be expected. If criminal proceedings were carried out in another country contrary to internationally recognised standards of fair trial, criminal proceedings may be instituted only with the authorisation from the Attorney General.*

*(7) In the case referred to in Articles 14, 15, 16 and 17 of this Code criminal proceedings shall be instituted only if the perpetrator is present on the territory of the Republic of Croatia.*

### 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.

*According to the Croatian internal law a legal person may be held liable for an offence established in accordance with Article 11 of the MEDICRIME Convention. In the Republic of Croatia the liability of legal persons for criminal offences is criminal liability.*

*The preconditions of punishability of legal persons are prescribed by the following Articles of the Act on the Responsibility of Legal Persons for Criminal Offences (Official Gazette nos 151/03, 110/07, 45/11, 143/12, hereinafter: the ARLPCO).*

*The Grounds for the Responsibility of Legal Persons*

*Article 3 of the ARLPCO*

*(1) A legal person shall be punished for a criminal offence committed by the responsible person if thereby a duty of that legal person is violated or if the legal person thereby obtained or should have obtained unlawful pecuniary advantage for itself or another.*

*(2) Under the conditions referred to in paragraph 1 of this Article, a legal person shall be punished for criminal offences prescribed by the Criminal Code and other laws in which criminal offences are prescribed.*

*The Responsible Person*

*Article 4 of the ARLPCO*

*The responsible person within the meaning of this Act is the natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided*

*Assignment of Guilt of the Responsible Person to the Legal Person*

*Article 5 of the ARLPCO*

*(1) The responsibility of the legal person is based on the guilt of the responsible person.*

*(2) The legal person shall be punished for a criminal offence committed by the responsible person even if the existence is established of legal or material hindrances for establishing the responsibility of the responsible person.*

*The liability of the legal person is without prejudice to the criminal liability of the natural person who have committed the offence, and this is conclusive from Article 5 paragraph 2 of the ARLPCO, as well as from the Article 23 of the ARLPCO, which reads:*

*Joined procedure*

*Article 23 of the ARLPCO*

*(1) For a criminal offence committed by the legal person and the responsible person, joined proceedings shall be conducted and a single judgement shall be passed.*

*(2) If no criminal proceedings may be instituted or conducted against the responsible person for legal or any other reasons whatsoever, the proceedings shall be instituted and conducted against the legal person only.*

*Under the ARLPCO the basis of criminal responsibility of legal person is a criminal offence comitted by responsible person of legal person. Responsibility of legal person is based on the guilt of the responsible person (Article 5 of the ARLPCO).*
*Responsible person within the meaning of the ARLPCO is a natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided (Article 4 of the ARLPCO).*
*In accordance with the prescribed legal definition, responsible person is not only a natural person in a leading position who conducts the affairs of legal person (e.g. member of supervisory board), but also a natural person who is under the authority of a person in a leading position, to whom running of affairs from the sphere of activity of legal person has been confided. This is the so-called extended /delegation (derived) model of liability of legal persons in which the liability of a legal person is based on the actions of not only members of the management and supervisory board but also persons ranked lower in the decision-making hierarchy, provided that they are entrusted with conducting the affairs from the scope of operation of legal person.*

*The basis of criminal responsibility of legal person is the fact that a responsible person violated any of the duties of the legal person or the fact that the legal person obtained or should have obtained unlawful pecuniary advantage for itself or third person by criminal offence committed by a responsible person (Article 3 of the ARLPCO).*

*Article 11 paragraph 2 of the MEDICIRME Convention prescribes the criminal liability of legal person where the lack of supervision or control by any natural person, acting either individually or as part of an organ of the legal person, and having a leading position within the legal person, has made possible the commission of an offence established in accordance with the MEDICIRME Convention for the benefit of that legal person by a natural person acting under its authority.*

*Subsequently, based on Article 3 in the acquisition with Article 4 and 5 of the ARLPCO if a natural person under the authority of a natural person in leading position, commits intentionally criminal offence for the benefit of the legal person, as a consequence of lack of supervision or control of a natural person in leading position, the liability of legal person will be based on the guilt of a natural person who is not a person in leading position, but has the capacity of responsible person under Article 4 of the ARLPCO and the guilt of the natural person in leading position which had made possible the commission of the criminal offence by the lack of supervision or control. Thus, the model of liability of legal persons for criminal offenses in Croatian legislation, according to which criminal offence may be committed by acting or by omitting to act, is fully in line with the requirements of Article 11 of the MEDICRIME Convention.*

### 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**);

*When prescribing sanctions for each criminal offence the legislator takes into consideration severity of that criminal offence in abstracto. In each particular case the court shall pronounce the punishment by taking into consideration the severity of the commited criminal offence in concreto and, within the limits set by the CC, determine and pronounce the punishment on the basis of Article 47 of the CC taking into account all circumstances affecting the severity of punishment by type and measure (mitigating and aggravating circumstances).*

*The prescribed criminal sanction for natural persons convicted of the criminal offence Counterfeiting of Medicines or Medical Products (Article 185 of the CC) is imprisonment.*

*According to the ARLPCO, types of punishments that may be imposed on the legal persons are fine and abolition of the legal person (Article 8 of the ARPLCO). The court may impose a suspended sentence on the legal person (Article 13 of the ARLPCO). Along with the punishment, the court may impose one or more of the following security measures on the legal person: prohibition of performing certain activities or work, prohibition of obtaining permits, powers, concessions or subsidies, prohibition of doing business with beneficiaries of the state budget or local budgets, and confiscation of objects (Article 15 of the ARLPCO).*

*Sanctions prescribed for the commission of the criminal offence referred to in Article 185 of the CC are criminal sanctions. Sanctions that may be imposed on the legal person for commission of the criminal offence are also criminal sanctions.*

*In relation to Article 12 paragraph 3 of the MEDICRIME Convention we would like to point towards paragraph 7 of the Article 185 of the CC, which prescribes, as follows:*
*(7) Products and means of production shall be confiscated.*

*Also, the objects may be confiscated on the basis of Article 79 of the CC, which applies to all criminal offences prescribed by the CC, and it states, as follows:*

*Confiscation of Objects*

*Article 79 of the CC*

*(1) The objects and means which are the products of criminal offence shall be confiscated.*

*(2) The court may confiscate objects and means which were intended to be used or were used in the commission of a criminal offence.*

*(3) The court may confiscate objects and means referred to in paragraph 1 and 2 of this Article also in cases where the perpetrator of the unlawful act is not guilty.*

*(4) The confiscated objects and means shall become the property of the Republic of Croatia. This does not affect the rights of third parties to claim damages against the perpetrator for the confiscation of an object or a means. Unless at least his/her gross negligence has contributed to the object or means being intended to be used or being used in the commission of a criminal offence or to its being the product of commission of a criminal offence or if he/she procured the object or means knowing about the conditions allowing for its confiscation, the owner of the confiscated object or means who is not the perpetrator of the offence is entitled to the return of the object or means or to damages equal to its market value paid from the state budget.*

*(5) Unless otherwise provided for in a special act, the law may prescribe mandatory confiscation of an object or means, in which case the owner shall not be entitled to damages paid from the state budget.*

*(6) The court may order the destruction of the confiscated object or means.*

*The pecuniary advantage acquired from the commission of the criminal offence referred to in Article 185 of the CC shall be confiscated on the basis of Article 5 and 77 of the CC, which apply to all criminal offences prescribed by the CC.*

*Principle of Confiscation of the Pecuniary advantage*
*Article 5 of the CC*

*No one shall retain the pecuniary advantage acquired from an unlawful act.*

*Conditions for and Manner of Confiscation of Pecuniary Advantage*

*Article 77*

*(1) Pecuniary advantage shall be confiscated on the basis of a court decision establishing the commission of an unlawful act. Pecuniary advantage shall also be confiscated from the person to whom it was transferred if it was not acquired in good faith.*

*(2) If the injured party has been awarded a material claim which by its nature and contents corresponds to the acquired pecuniary advantage, the part of pecuniary advantge exceeding the awarded material claim shall be confiscated.*

*(3) The court shall confiscate the pecuniary advantage also in cases where it has instructed the injured party to assert his or her material claim in a civil action.*

*(4) Where it has been established that confiscation in full or in part of objects or rights acquired as pecuniary advantage is impossible, the court shall order the perpetrator to pay the corresponding money equivalent. It may be ordered that payment be made in instalments.*

*(5) The confiscated pecuniary advantage shall not be reduced by the value of resources invested in the criminal activity.*

*(6) The court may decide against the confiscation of pecuniary advantage if its value is negligible.*

*In case the criminal offence referred to in Article 185 of the CC is committed within the framework of the criminal organization, the Article 78 of the CC shall also apply.*

*Extended Confiscation of Pecuniary Advantage*

*Article 78*

*(1) Unless otherwise prescribed by this Article, the provisions of Article 77 of this Code shall apply to the extended confiscation of pecuniary advantage acquired by criminal offence for which the Office for the Suppression of Corruption and Organised Crime is competenet and by criminal offences prescribed by Titles XVII. an XXV. of this Code, if pecuniary advantage was acquired by those criminal offences.*

*(2) If the perpetrator of a criminal offence refferd to in paragraph 1 of this Article posseses or possesed property that is disproportionate with his or her legitimate income and unless he or she makes it probable that the property is of legitimate origin, it is presumed that such property constitutes a pecuniary advantage.*

*(3) If the pecuniary advantage from a criminal offence have been merged into legitimately acquired property, the entire property shall be subject to confiscation up to the estimated value of the pecuniary advantage. The advantage acquired from property in which the legitimately acquired property was merged with the pecuniary advantage shall also be confiscated in the same manner and in the same ratio.*

*(4) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall be confiscated from a family member irrespective of the legal basis on which he or she possesses it and regardless of whether he or she lives in a shared household with the perpetrator.*

*(5) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall also be confiscated from another person irrespective of the legal basis on which it was acquired unless this person makes it probable that he or she acquired the advantage in good faith and at a reasonable price.*

*(6) If the person against whom criminal proceedings have been instituted dies, the pecuniary advantage acquired by an unlawful act may be confiscated from his or her successors in proceedings prescribed by a special act.*

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**).

*Final sentences passed by another Party in relation to the offences of the same nature may be taken into account when determining the sanction according to Article 47 paragraph 1 of the CC. This provision is located in the General part of the CC and, according to Article 6 of the CC, it applies to all criminal offences prescribed by the CC.*

*Determination of Punishment*

*Article 47 of the CC*

*(1) When determining the type and range of punishment, the court shall, starting from the degree of culpability and the purpose of punishment, assess all the circumstances affecting the severity of punishment by type and range (mitigating and aggravating circumstances), and especially the degree of threat to or violation of a legally protected good, motives for having committed the criminal offence, degree to which the perpetrator's duties have been violated, manner of commission and the inculpatory consequences arising from the commission of the criminal offence, perpetrator's prior life, his or her personal and pecuniary circumstances and his or her conduct following the commission of the criminal offence, relationship to the victim and efforts to compensate for the damage.*

*International recidivism Criminal records are kept for natural and legal persons who have been sentenced for criminal offenses in the Republic of Croatia. Criminal records are also kept for nationals of the Republic of Croatia and for legal persons with headquarters in the Republic of Croatia who for criminal offenses are legally convicted outside the Republic of Croatia if these data are submitted to the Ministry (Law on Legal Consequences of Judgment, Criminal Records and Rehabilitation, Official Gazette nos.143/12, 105/15, 32/17). Regarding the EU Member States, data is transmitted through the ECRIS system, and regarding other countries data is submitted on the basis of bilateral agreements (typically every 6 months). Once data is inscribed in criminal records, for courts there is no difference between final decisions brought by domestic courts or those brought by courts of another Party, when determining the sentence. Consequently, it means that there is not only possibility but obligation to take into account final decisions against natural or legal persons taken in another Party when determining the penalty.*

*Criminal records are kept in the Ministry of Justice and administration of the Republic of Croatia in such a manner as to enable the courts and the State Attorney's offices to have direct access to data in real time (Criminal Procedure Act, Article 185).*

*Although the Article 14 of the Convention does not place any positive obligation on courts or prosecution services to take steps to find out whether persons being prosecuted have received final sentences from another Party's courts, in practice when the prosecutor´s office obtains information (usually through the channels of police international cooperation) that the defendant has already been convinced in another country and the criminal records does not contain this information (for example the defendant is not Croatian citizen), the prosecutor issues the MLA request in accordance with the MLA Convention signed on 1959 or request in accordance with the provisions of Council Framework Decision 2008/675/JHA ( "ECRIS Framework Decision") depending on the fact whether the requested country is Third country, MS EU that has implemented the ECRIS Framework Decision or MS EU that has not implemented the ECRIS Framework Decision.*

*We would also like to emphasize that the Article 3 paragraph 1 ECRIS Framework Decision reads as follows: "Each Member State shall ensure that in the course of criminal proceedings against a person, previous convictions handed down against the same person for different facts in other Member States, in respect of which information has been obtained under applicable instruments on mutual legal assistance or on the exchange of information extracted from criminal records, are taken into account to the extent previous national convictions are taken into account, and that equivalent legal effects are attached to them as to previous national convictions, in accordance with national law. "*

*Please note that the ECRIS Framework Decision is implemented in the national legislation by above mentioned Law on Legal Consequences of Judgment, Criminal Records and Rehabilitation and other relevant procedural laws (Criminal Procedure Act and Act on mutual legal assistance in criminal matters).*

### 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**).

*Circumstances referred to in Article 13 paragraphs b), c) and d) of the MEDICRIME Convention are constituent elements of the qualified form of the criminal offence Counterfeiting of Medicines or Medical Products referred to in Article 185 paragraph 5 of the CC.*

*Circumstances referred to in Article 13 paragraphs a), e) and f) of the MEDICRIME Convention may be taken into consideration in the determination of sentence according to Article 47 paragraph 1 of the CC. This provision is located in the General part of the CC and, according to Article 6 of the CC, it applies to all criminal offences prescribed by the CC.*

*Determination of Punishment*

*Article 47 of the CC*

> *(1) When determining the type and range of punishment, the court shall, starting from the degree of culpability and the purpose of punishment, assess all the circumstances affecting the severity of punishment by type and range (mitigating and aggravating circumstances), and especially the degree of threat to or violation of a legally protected good, motives for having committed the criminal offence, degree to which the perpetrator's duties have been violated, manner of commission and the inculpatory consequences arising from the commission of the criminal offence, perpetrator's prior life, his or her personal and pecuniary circumstances and his or her conduct following the commission of the criminal offence, relationship to the victim and efforts to compensate for the damage.*

### 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**).

*Criminal offence referred to in Article 185 of the CC shall be prosecuted ex officio.*

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**).

*Please see our answer on the question marked as 11. a. of this questionnaire.*

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**).

*For the purpose of financial investigations, we point to the Article 206i of the CPA. Paragraph 1 of that Article prescribes that if there are grounds for suspicion that a criminal offence prosecuted ex officio was committed and that a pecuniary advantage was obtained by it, the State Attorney shall without delay conduct or order the conduct of inquiries in order to establish the value of such advantage and the location of the property thus obtained. If the pecuniary advantage obtained by means of a criminal offence was concealed by the perpetrator or if there are grounds to suspect money laundering, the State Attorney shall do whatever is necessary to locate the said property and ensure its confiscation. According to paragraph 2, in the case of criminal offences falling within the jurisdiction of the county court, with respect to which there are grounds to suspect that a considerable pecuniary advantage has been obtained, financial investigators, state attorney office advisors and expert associates from a special department within the State Attorney's Office investigating the proceeds of crime shall take part in the conduct of inquiries and the taking of the urgent evidentiary action of temporary seizure of an object. The Department shall conduct inquiries in consultation with and by order of the State Attorney with a view to establishing the value of property and ensuring the confiscation and the locating of criminal property. According to paragraph 3, If there are grounds for suspicion that a considerable pecuniary advantage was obtained, the State Attorney shall request from the head of the police and the competent administrative authorities of the Ministry of Finance to place at his disposal officers who will take part under his supervision in the conduct of joint inquiries referred to in paragraph 2 of this Article. During the period of their taking part in joint activities, the said officers shall act on the orders of the State Attorney and shall be accountable to him for their work. On the need for officer secondments the State Attorney shall consult with the Police Directorate and the Ministry of Finance. Paragraph 4 prescribes that any government authority and any legal person that within their sphere of activity or scope of work learn of any circumstance or fact pointing to property having been acquired by a criminal offence within the framework of legal transactions, in particular where the activities involving the acquired financial resources or property point to money laundering or the concealment of such property, shall without delay inform the State Attorney of the said circumstances or facts. On the basis of Paragraph 5, where as a result of the inquiries conducted under paragraphs 1, 2 and 3 of this Article the necessary facts and information on the amount of pecuniary advantage obtained are gathered or where the location of such property is established, the State Attorney shall without delay file a motion for the ordering of the temporary security measure against the concealment or destruction of such property. He shall also in the indictment or no later than at the preliminary hearing file a motion that the said property be confiscated.*

*We also point to the Article 334 point 3 of the CPA, according to which the special evidentiary actions referred to in Article 332, paragraph 1 of the CPA may be ordered for, among others, for the criminal offence of falsification of medicinal products or medical devices (Article 185 of the CC). We also refer to our answer on the questions marked as 6. a. and 6. b. of this questionnaire.*

*Furthermore, we refer to the Article 332 paragraph 1 of the CPA. According to that provision, where the inquiries into criminal offences cannot be carried out in any other way or where this would entail disproportionate difficulty, the judge of investigation may, upon a written reasoned motion of the State Attorney, issue against the person suspected of having committed the*

*criminal offence referred to in Article 334 of the present Act alone or of having participated together with other persons in its commission a written reasoned warrant for the taking of special evidentiary actions temporarily restricting certain constitutional rights of citizens, namely:*

*1) the surveillance and technical recording of telephone conversations and other remote communications;*
*2) the interception, collection, and recording of computer data;*
*3) entry into premises for the purpose of surveillance and the technical recording of the premises;*
*4) covert tailing and technical recording of persons and objects;*
*5) the use of undercover investigators and confidants;*
*6) simulated selling and purchasing of objects, simulated bribe-giving and simulated bribe-taking;*
*7) the provision of simulated business services or the conclusion of simulated legal transactions;*
*8) supervised transport and delivery of the objects of a criminal offence.*

### 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.

*In reference to the access to information relevant to the case of the victim, we point to the Article 184 paragraph 2 of the CPA. According to this provision, the victim, injured party and their proxies shall have the right to inspect the case file. If prior inspection of the case file would influence the testimony of the victim or the injured party, they shall have the right to inspect the case file only after they have been examined.*

*According to the Article 43 paragraph 1 points 1 and 2 of the CPA, in part in which it concerns the measures taken to assist victims in their physical, psychological and social recovery, a victim has the right to access services providing support to victims of criminal offences and the right to efficient psychological and other professional assistance and support of the body, authority or institution providing assistance to victims of criminal offences as provided for by law.*

*Regarding the measures to provide for the right of victims to compensation from the perpetrators, according to the Article 46 paragraph 1 of the CPA the victim shall be entitled to register as an injured party with the police or the state attorney's office before the indictment is preferred and with the court before the trial ends.*

*Furthermore, according to the Article 153 paragraph 1 of the CPA a claim for indemnification arising out of the commission of a criminal offence shall be considered in criminal proceedings upon the motion of authorized persons, provided that this does not considerably delay proceedings. The claim for indemnification may consist of an issue which may be litigate in a civil action.*

*Article 154 paragraph 1 of the CPA prescribes that the indemnification motion made in a criminal proceeding may be filed by the injured party.*

*According to the Article 158 of the CPA the court shall have jurisdiction to decide on claims for indemnification. The court may in a judgement of conviction satisfy the claim of the injured person fully, or it may satisfy it partially while directing the injured person to assert the rest of the claim in a civil action. If the data established in criminal proceedings furnish no reliable basis for either full or partial adjudication, the court shall direct the injured person to assert his claim in a civil action. When rendering a judgement of acquittal, a judgement rejecting the charge, or a ruling discontinuing criminal proceedings, the court shall direct the injured person to assert his claim for indemnification in a civil action. When the court declares itself incompetent, it shall instruct the injured person that he may assert his claim for indemnification in criminal proceedings which shall be instituted or continued by a court having jurisdiction.*

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**).

*We note that the protection of the victims, as well as their rights, including the rights of an injured party is guaranteed throughout the whole criminal proceedings. Article 16 of the CPA guarantees that the victim and the injured person shall have the rights in criminal proceedings pursuant to CPA. It provides for the obligation of the police, the investigator, the State Attorney's Office and the court to treat with special consideration any victim of a criminal offence. These bodies are in obligation to instruct the victim and the injured party of their rights in the proceedings in accordance with the CPA. When taking any action, they shall take adequate care that the said persons' rights are being respected. Article 43 paragraph 1 points 8 and 9 of the CPA provide the victim with a right to file a motion for prosecution and a private action pursuant to the provisions of the CC, the right to participate in the criminal proceeding as an injured party, the right to be informed of the dismissal of the criminal complaint (Article 206, paragraph 3 of the CPA) and of the state attorney dropping the criminal charge, and the right to take over criminal prosecution in lieu of the state attorney, as well as the right to be informed by the state attorney of the acts performed as a result of his/her complaint (Article 206a of the CPA) and the right to complain to a senior state attorney (Article 206b of the CPA). Article 43 paragraph 1 point 11 of the CPA gives a victim the right to be informed, at his/her request, of any decision finally terminating a criminal proceeding. Article 43 paragraph 4 of the CPA obliges the court, the state attorney's office, the investigators and the police shall advise the victim in a manner he/she understands of his/her rights reffered in Article 43 paragraph 1 of the CPA, which comprises of the list of rights any victim is entitled to, as well of their rights reffered in the Article 43 paragraph 2 and 3, which pertain to the professional assistance of an advisor appointed at government expense when bringing a civil claim to compensation from the state budget, if the conditions are met. These bodies are also obliged to inform the victim of his/her rights guaranteed under the Article 44 of the CPA, which provides for the further rights of the victims, in case a victim is a child, or if victim of the criminal offence against sexual freedom and victims of the criminal offence of human trafficking is in question, as well as the rights of the victim if a specific protective needs have been established. These bodies also have the obligation to instruct the victim of his/her rights as an injured party and they must treat the victim in a considerate manner and shall make sure that he/she has understood the*

*information given to him/her about his/her rights, as well as instruct him/her in a manner he/she understands on what it means to participate in a proceeding as the injured party. The instruction given and the statement by the victim on whether he/she wants to take part in the proceeding as the injured party shall be entered on the record. Under the Article 46 paragraph 1 of the CPA the victim is entitled to register as an injured party with the police or the state attorney's office before the indictment is preferred and with the court before the trial ends. According to the Article 51 paragraph 1 point 8 and 11 of the CPA the victim that has registered as an injured party shall have the right to request to be informed by the state attorney of the acts performed following his/her complaint (Article 206a of CPA) and to file a complaint to the senior state attorney (Article 206b of CPA) and to be informed of the outcome of the criminal proceeding. Article 206a of the CPA gives the right to the victim and injured party to request from the State Attorney to be informed of the actions taken pursuant to the crime report or the report on a committed offence upon expiry of two months from the submission of the crime report or the report on a committed offence Unless the efficiency of proceedings would thereby be jeopardised, the State Attorney shall inform them within reasonable time and no later than thirty days from receipt of request of the actions taken. Of the denial to provide information the State Attorney shall inform the victim and the injured party that requested the said information. If the State Attorney fails to inform the victim or the injured party or if the victim or the injured party are not satisfied with the information provided or the actions taken, they shall have the right to file a complaint to the senior State Attorney. The senior State Attorney shall verify the allegations made in the complaint and if he establishes that the complaint is well-founded, he shall order the lower-ranking State Attorney to deliver to the person that lodged the complaint the requested information on the actions taken or to take within reasonable time any action which should have been taken. If the senior State Attorney establishes that as a result of the acts of the lower-ranking State Attorney the rights of the person that lodged the complaint have been violated, he shall inform the latter thereof and in doing so specify which rights have been violated. Unless they have lodged a complaint with the senior State Attorney referred to in Article 206b, paragraph 2, of the CPA, the victim and the injured party may upon expiry of six months from the previously submitted request for information on the actions taken request anew to be informed whether the actions set forth in paragraph 1 of this Article have been taken. Furthermore, Article 206b of the CPA obliges the State Attorney to decide on the crime report within six months from the date of the entry of the crime report on the crime report register and to inform the person that submitted the crime report of his decision accompanied by a brief explanation of the reasons therefore.*

*Upon expiry of the time limit referred to in paragraph 1 of this Article or upon expiry of six months after the State Attorney proceeded pursuant to Article 205, paragraph 5, of the present Act, the person that lodged the complaint, the injured party or the victim may lodge a complaint to the senior State Attorney concerning the State Attorney's failure to take action, as a result of which failure the proceedings have been delayed.*

*Upon having received the complaint referred to in paragraph 2 of this Article, the senior State Attorney shall without delay request a response to the allegations made in the complaint. If he deems the complaint to be well-founded, the senior State Attorney shall set a reasonable time limit by which the decision on the report is to be taken. Within fifteen days from the day of receipt of the complaint the senior State Attorney shall inform the person that lodged the complaint of the steps taken. If the complaint is not acted on within the time limit referred to in paragraph 4 of this Article, the person that lodged the complaint may re-lodge it.*

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)**);

*Article 43 paragraph 1 points 4 and 5 of the CPA prescribe that the victim has the right to protection of the dignity of the victim when testifying and the right to be heard without unjustified delay after the complaint with regard to a criminal offence has been made and to be further heard only insofar as this is necessary for the purposes of the criminal proceeding.*

*According to the Article 43a paragraphs 1 and 2 of the CPA, before questioning the victim, the body conducting the questioning shall carry out, in cooperation with the bodies, organisations or institutions providing assistance and support to victims of criminal offences, an individual assessment of the victim. The individual assessment shall include establishing whether there is a need to take special protection measures in respect of the victim and if yes, which ones (special method of questioning the victim, use of communication technology so as to avoid visual contact between the victim and the perpetrator and other measures provided for by law). Where the victim of a criminal offence is a child, it shall be presumed that special protection measures need to be taken and it shall be established which ones. The individual assessment of a victim shall take into account the personal characteristics of the victim, the type or nature of the criminal offences and the circumstances of the criminal offence. In this context particular attention shall be paid to victims who have suffered considerable harm due to the severity of the criminal offence, victims of a criminal offence committed with a bias related to their personal characteristics and victims whose relationship to the perpetrator makes them particularly vulnerable.*

*Furthermore, on the basis of the Article 44 paragraph 5 point 1 of the CPA, in addition to the rights enjoyed by the victim under Article 43 of CPA, a victim with specific protection needs as provided for in Article 43a of the CPA of this Act shall have, the right to before being questioned, to counselling services at government expense.*

*According to the Article 46 paragraph 1 of the CPA the victim shall be entitled to register as an injured party with the police or the state attorney's office before the indictment is preferred and with the court before the trial ends.*

*On the basis of the Article 51 paragraph 1 points 3, 4, 5 and 6 of the CPA the injured party has the right to an attorney-in-fact, the right to draw attention to facts and produce evidence, the right to be present at the evidentiary hearing and the right to be present at the trial, take part in the submission of evidence and deliver a closing argument.*

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)**)

*The Ministry of Justice and Administration has a leading role in the institutionalization of the victim and witness support system within the judiciary, and coordinates the victim and witness support system in the Republic of Croatia, which operates at three levels;*

*1. at the level of the Ministry of Justice and Administration there is a Victim and Witness Support Service*

*2. at the level of courts there are Victim and Witness Support Departments established at seven county courts and*

*3. at the level of civil society organizations providing support to victims and witnesses, there is a Network funded by the Ministry of Justice and Administration and National Call Center.*

*The Victim and Witness Support Service at the Ministry of Justice and Administration carries out the tasks of:*

*1. Coordination of the Victim and Witness Support system in general and Coordination of the National Committee for Monitoring and Development of Victim and Witness Support System*

*2. Provision of information to victims about the release of prisoners from serving a prison sentence pursuant to the Law on Execution of Prison Sentences*

*3. Provision of information and support to victims and witnesses in cross border cases, information about the rights in written form, information and support provided over the phone, referral to other relevant services*

*4. Provision of compensation to victims and administrative and technical tasks for the Committee for Financial Compensation for Victims of Crimes, which deals with application for financial compensation to victims, in accordance with the Law on Financial Compensation for Victims of Crimes*

*5. Coordination of the Victim and Witness Support Departments at the courts*

*Victim and witness support departments (County courts in Zagreb, Osijek, Sisak, Vukovar, Zadar, Split and Rijeka) provide emotional support, information on victims' rights, general procedural information, technical and practical information - before, during and after criminal proceedings, and refer victims and witnesses to specialized institutions and civil society organizations depending on their needs. Victims and witnesses may contact the departments by telephone, e-mail or may come in person with prior notice. Support is provided at the county, municipal and misdemeanor courts.*

*6. Monitoring the work of the National Call Centre for Victims of Crime - 116 006, which provides information and support to victims of crimes and offenses established by the Ministry of Justice in cooperation with the Association for Victim and Witness Support. Call Center is established under the Decision of the European Commission of 15 February 2007 on reserving the national numbering range that begins with '116' for harmonized numbers services of social value (2007/116 / EC).*

*National Call Center provides a free service: inform victims of their rights and ways of their realization, emotional support, and refer victims to other institutions and organizations that can provide them with professional assistance. National Call Center for Victims of Crime and Misdemeanors 116 006 is available for the entire territory of the Republic of Croatia every working day from 08:00 to 20:00.*

*4. For the purpose of expanding the system of support for victims and witnesses and providing support to citizens throughout the Republic of Croatia, the Ministry of Justice prompted the establishment and financing of activities of a partner network of organizations for support and assistance to victims and witnesses "Network of support and cooperation for victims and witnesses of crimes", in counties where victim and witness support departments have not been established, which has been ongoing for a period of three years. Civil society organizations from the Network provide support to victims and witnesses of crimes and misdemeanors. Network is funded from the resources of the games of chance, based on a public tender conducted by the Ministry of Justice and Administration. Organizations involved in the Network provide information on rights, emotional support, psychological and legal counseling and, as a person of trust, provide escort to competent courts and other relevant institutions in counties in which there are no established departments for support for victims and witnesses.*

*The bodies of criminal and misdemeanor proceedings (police, public prosecutor's office, courts) are obliged to inform the victim about his/her rights and refer them to support services.*

*The police provide victims with a victim rights Form (special forms created for victims of different offences), including information on services and organizations (Victim Support Departments at the courts, National Call Centre and CSO's) providing free assistance and support.*

*Courts provide information and contact details of Support Departments at the court subpoena that is send to victims and witnesses.*

*The website of the Ministry of Justice and Administration contains information for Victims and Witnesses and there information on rights and criminal and misdemeanor proceedings (in form of questions and answers), followed by a brochure on the right to financial compensation in accordance with the Law on Financial Compensation for Victims of Crime and a claim form, a brochure "Guide to Victims and Witnesses through Criminal and Misdemeanor Proceedings" in Croatian and English language, leaflet of the Victims and Witness Support Department, which is also distributed to the competent bodies that come in contact with the victims and witnesses in their work.*

*https://pravosudje.gov.hr/o-ministarstvu/djelokrug-6366/iz-pravosudnog-sustava-6372/podrska-zrtvama-i-svjedocima/6156*

*Also in the Republic of Croatia there are other civil society organization providing help and support to different type of victims. More information is available at the web site of the Ministry of Justice and Administration*

*https://pravosudje.gov.hr/o-ministarstvu/djelokrug-6366/iz-pravosudnog-sustava-6372/podrska-zrtvama-i-svjedocima/kontakti-organizacija-koje-pruzaju-psihosocijalnu-i-pravnu-pomoc/19915*

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)**);

*Article 43 paragraph 1 point 3 prescribes that the victim has the right to protection from intimidation and retaliation.*

*According to the Article 43a paragraphs 1 and 2 of the CPA, before questioning the victim, the body conducting the questioning shall carry out, in cooperation with the bodies, organisations or institutions providing assistance and support to victims of criminal offences, an individual assessment of the victim. The individual assessment shall include establishing whether there is a need to take special protection measures in respect of the victim and if yes, which ones (special method of questioning the victim, use of communication technology so as to avoid visual contact between the victim and the perpetrator and other measures provided for by law). Where the victim of a criminal offence is a child, it shall be presumed that special protection measures need to be taken and it shall be established which ones. The individual assessment of a victim shall take into account the personal characteristics of the victim, the type or nature of the criminal offences and the circumstances of the criminal offence. In this context particular attention shall be paid to victims who have suffered considerable harm due to the severity of the criminal offence, victims of a criminal offence committed with a bias related to their personal characteristics and victims whose relationship to the perpetrator makes them particularly vulnerable.*

*Furthermore, on the basis of the Article 44 paragraph 5 paints 4, 5 and 6 of the CPA, in addition to the rights enjoyed by the victim under Article 43 of CPA, a victim with specific protection needs as provided for in Article 43a of the CPA of this Act shall have, the right to demand to be questioned via an audio-video link (Article 292, paragraph 4, of the CPA), the right to the confidentiality of personal information and the right to demand that the hearing be closed to the public.*

*On the basis of the Article 292 paragraph 3 of the CPA, witnesses who cannot obey the summons due to their old age, state of health or a disability may be examined in their dwellings or other premises where they are situated. These witnesses may be questioned by means of audio and video devices which are operated by an expert assistant. If required so by the condition of the witness, the questioning shall be organized in such a manner that the witness can be questioned by the parties without their presence in a room where the witness is situated. If necessary, the interrogation shall be video-taped and audio-taped, and the recording sealed and enclosed with the record. Paragraph 4 of that Article states that in the manner referred to in paragraph 3 of this Article, upon the witness' request, the examination may be carried out as the examination of a witness of a criminal offence against sexual freedom and the criminal offence of trafficking in human beings or if a criminal offence is committed in the family. Such witness may be re-examined only exceptionally and where deemed necessary by the court.The victim in respect of whom specific protection needs have been identified as provided for in Article 43a of this Act shall also be questioned in the manner set out in paragraph 3 of this Article where he/she so requests. According to paragraph 5 of the same Article, if the examination of a witness is carried out pursuant to paragraph 3 of this Article, it shall be proceeded pursuant to Article 297 paragraph 3 of this Act.*

*According to the Article 294 paragraph 1 of the CPA, if it is likely that by giving a testimony or by answering any individual question, a witness might expose himself or any other person close to himself to a serious danger to life, health, physical integrity, freedom or property of considerable volume (witness in danger), the witness is entitled to refuse to disclose*

*information referred to in Article 288, paragraph 2 of this Act, to refuse to answer to individual questions or to refuse to testify all until witness protection measures have been provided. Witness protection referred to in paragraph 1 of this Article includes a special manner of questioning a witness and his participation in the proceedings and measures for protecting the witness and other persons close to him not participating in the proceedings. The authority participating in the proceedings is bound to proceed with special care regarding witness protection. Special manners of questioning an endangered witness and of his participation in the proceedings are stipulated in this Act and may be implemented even before the commencement of the proceedings. Protection of a witness and other persons close to him not participating in the proceedings is prescribed in a special act.*

*Article 295 paragraph 1 of the CPA prescribes that as soon as he becomes aware of the probability of existence of circumstances referred to in Article 294 paragraph 1 of this Act, the State Attorney shall suggest to the investigating judge the implementation of a special manner of participation and examination of the witness. The State Attorney shall submit the suggestion to the investigating judge in a sealed cover with the note " Endangered witness - Confidential", whereof the witness shall be informed first. It shall be submitted personally or through an investigator. On the basis of paragraph 2 of this Article, the State Attorney shall specify in his suggestion a special manner of participation in the proceedings (summoning of the witness, appearing at the hearing, etc.) and a special manner of examination of the witness suggested as well as the reasons for suggesting them. Paragraph 3 of that Article states that the State Attorney may submit the suggestion referred to in paragraph 1 of this Article to the investigating judge before and during the examination. Should the defendant suggest the examination of a endangered witness, the State Attorney may submit a relevant suggestion to the investigating judge and should he disagree with the suggestion, he shall ask for a decision by the investigating judge. According to paragraph 4 of this Article, the judge of investigation shall reach a decision on the State Attorney's suggestion within twelve hours from the receipt of the suggestion. The State Attorney may file an appeal against the decision of the investigating judge denying the suggestion referred to in paragraph 1 of this Article. The panel shall decide on the appeal within twenty-four hours. If the investigating judge accepts the suggestion of the State Attorney, he shall, on the basis of paragraph 5 of this Article,*
*determine by a ruling: a pseudonym for the endangered witness, a special manner of participation in the proceedings (summoning, appearing before the court, etc.), a special manner of examination. According to the paragraph 9 of this Article, after the ruling on the special manner of participating in the proceedings and special manner of examination, the investigating judge shall schedule a hearing and shall question the endangered witness. During summoning, appearing of the protected witness, staying at and leaving the hearing the investigating judge and the State Attorney may order the police authorities to undertake measures of protecting the witness.*

*On the basis of the Article 296 paragraph 1 of the CPA, if the special manner of examination of a witness refers only to non-disclosure of information, the examination shall be carried out under a pseudonym without listing of other information referred to in Article 288 paragraph 2 of this Act. As regards its other parts, the examination of the endangered witness shall be carried out pursuant to the general provisions of this Act related to the examination of witnesses.*

*On the basis of the Article 297 paragraph 1 of the CPA, if the special manner of examination of an endangered witness refers not only to non-disclosure of information referred to in Article 288 paragraph 2 of this Act but also to non- disclosure of physical appearance of the witness, the examination shall be carried out by using audio and video devices. The audio and video devices shall be operated by an expert person. The appearance and the voice of the witness shall be changed during the examination. In the course of examination, the witness shall be situated in a room that is separated from the room in which the investigating judge and other persons attending the examination are situated. The examination shall be conducted pursuant to Article 292 paragraph 3 of this Act.*

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**).

*According to the Article 59 paragraph 1 of the CPA, the subsidiary prosecutor at whose request a proceeding for a criminal offence punishable under the law by a term of imprisonment of more than five years is conducted may be appointed, upon request, an attorney-in-fact where the interests of the proceeding so require and if the subsidiary prosecutor's financial condition makes it impossible for him/her to bear the costs of legal representation.*

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**)

The following act and ordinance have been enacted to establish the quality, efficacy and safety requirements of medical products:

- *Medicinal Products Act*
- *Medical Devices Act*
- *Ordinance on granting marketing authorisation for medicinal products*

- *Ordinance on essential requirements, classification, registration of manufacturers in the register of medical device manufacturers, registration of medical devices in the register of medical devices and conformity assessment of medical devices*

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

*The following ordinances have been enacted to ensure the safe distribution of medical products:*

- *Ordinance on good practice in the distribution of medicinal products, on issuing authorisation for wholesale distribution of medicinal product, registration for brokering of medicinal products and on issuing certificates on good practice in wholesale distribution of medicinal products*
- *Ordinance on the requirements and method of establishing the requirements of good manufacturing practice and good practice in the wholesale of active substances and on the procedure of the entry in the register of manufacturers, importers and wholesalers of active substances, and on issuing the certificate for the implementation of good manufacturing practice*
- *Ordinance on good practice in the wholesale of medical devices and conditions for entry in the register of wholesale distributors of medical devices*
- *Ordinance on essential requirements, classification, registration of manufacturers in the register of medical device manufacturers, registration of medical devices in the register of medical devices and conformity assessment of medical devices*
- *Ordinance on conditions for performing retail sale and granting permits to specialised shops for the retail sales of medical devices*

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 issue of the counterfeit medicines has been one of the main topics addressed at the HALMED's annual regulatory and pharmacovigilance conferences, along with the implementation of safety features. In 2012 HALMED organized a regional SPOC training for health, police and customs authorities in cooperation with Council of Europe.*

*In past years HALMED has also organized trainings for wholesalers.*

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

*Medicinal Products Act*

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**);

*Croatian Agency for Medicinal Products and Medical Devices (HALMED) continuously conducts awareness rising activities. HALMED has been continuously highlighting risks of buying counterfeits online. HALMED regularly provides media statements and takes part in television and radio shows on falsified medicines and threats of buying medicines on the Internet. In addition, number of articles about falsified medicines and the threat of buying medicines on the Internet are published in daily and weekly publications and on newsportals based on the information HALMED provides to the media and through its website.*

*The issue of the counterfeit medicines has also been one of the main topics addressed at the HALMED's annual regulatory and pharmacovigilance conferences, along with the implementation of safety features.*

*HALMED regularly publishes news relating to falsified medicines, including the news on INTERPOL's Operation Pangea, on its website.*