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**GENERAL OVERVIEW QUESTIONNAIRE  
ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION**

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**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**  
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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<sup>1</sup> (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<sup>2</sup>.*

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*

<sup>1</sup> 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.

<sup>2</sup> 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)<sup>3</sup>, 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”?

Yes. In the Republic of Slovenia, the area is governed by two sectoral laws, namely the Medicinal Products Act (ZZdr-2), the Medical Devices Act (ZMedPri) and Decree on the implementation of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Reg-MDR). Legislation that we apply at national level for medicinal products and medical devices does not define the term “medical product” in the way it is in the MEDICRIME Convention. In national legislation, the definitions “medicinal product” and “medical devices” are understood and used as a common term for “medical product” which include both drugs and medical devices and documentation. The term “medical product” is used in Resolution on the national program for the prevention and suppression of crime 2019–2023 (ReNPPZK19–23) and in Article 183.a of the Criminal Code (KZ-1), which implements the Convention, criminalizes manufacturing, preparation, production, selling or offering for sale or buying or storing for the purpose of sale or putting on the market, or serving as an agent in the sale or purchase, importing or exporting, inputting or outputting or otherwise putting on the market medicinal products, as well as medical devices that are counterfeited/falsified.

- 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”?

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<sup>3</sup> As envisaged in Art. 2 of the MEDICRIME Convention.

Yes. The definition of "medicinal product" from point b) of Article 4 of the Convention corresponds to the definition of medicinal product in Article 5 of the ZZdr-2.

- 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"?

Yes. The ZZdr-2, as a sectoral law, explicitly and independently define "active substances". Article 183.a of the KZ-1, which implements the Convention, criminalizes manufacturing, preparation, production, selling or offering for sale or buying or storing for the purpose of sale or putting on the market, or serving as an agent in the sale or purchase, importing or exporting, inputting or outputting or otherwise putting on the market (besides medicinal products and medical devices) also active substances that are counterfeited. The explanations also provide a definition that is consistent with the Convention.

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

Yes. The ZZdr-2, as a sectoral law, explicitly and independently define "excipients". Article 183.a of the KZ-1, which implements the Convention, criminalizes manufacturing, preparation, production, selling or offering for sale or buying or storing for the purpose of sale or putting on the market, or serving as an agent in the sale or purchase, importing or exporting, inputting or outputting or otherwise putting on the market (besides medicinal products, medical devices, active substances) also excipients that are counterfeited/falsifying. The explanations also provide a definition that is consistent with the Convention.

- 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"?

#### **AD e., f., g.:**

In relation to the "medical devices", "accessory", "parts" and "materials", the appropriate definition of medical devices is in Article 3 of the ZMedPri and definitions in Article 2 of the Reg-MDR.

They are also included in the incrimination according to the first paragraph of Article 183.a of KZ-1, which reads in its entirety as follows:

"Article 183.a

(1) Whoever manufactures, prepares, produces, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or serves as an agent in the sale or purchase, imports or exports, inputs or outputs or otherwise puts on the market medicinal products, active substances, excipients, medical devices or their parts or accessories or other healing remedies that are counterfeited, and has not

committed a more serious criminal offence according to this Code, shall be sentenced to imprisonment for not more than five years.  
.....”

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

Yes, please, see answer to point e.

- 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”?

Yes, please, see answer to point e.

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

Yes. Documentation of medicinal products and medical devices is precisely regulated by ZZdr-2, and ZMedPri and Reg-MDR. According to KZ-1 a document is any writing, data carrier or other object appropriate and intended to produce evidence on any fact relevant to legal relations.

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

Yes. ZZdr-2 regulates the field of medicinal products for human use and veterinary medicinal products, the conditions and measures to ensure their quality, safety and efficacy, conditions and procedures for their testing, the production, distribution and use of medicinal products, the prices of medicinal products, official controls, advanced therapy medicinal products prepared on a non-routine basis, and supervision of the implementation of this Act with the aim of public health protection for medicinal products that are industrially produced or manufactured in a manner involving an industrial process, including pre-mixes for preparing medicated compound feeding stuffs, with active substances used as starting materials, and for certain substances which may be used as veterinary medicinal products, and having anabolic, anti-infection, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties, and the tasks and competences of the Public Agency of the Republic of Slovenia for Medicines and Medical Devices (hereinafter referred to as: JAZMP). The Reg-MDR lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. Reg-MDR also applies to clinical investigations concerning such medical devices and accessories conducted in the Union, general obligations of manufacturers.

- j. Does the understanding of “counterfeit” under your internal law correspond to that set out in **Article 4, letter (j)**, i.e. “a false representation as regards identity and/or source”?

YES

Yes. By ZZdr-2 definition of “falsified medicinal product” is any medicinal product with false presentation of:

- identity, including its packaging and labelling or name or composition of any of the ingredients, including excipients, and strength;
- its source, including the manufacturer, country of manufacture, country of origin or the marketing authorization holder; or
- history, including records and documentation on the distribution channels used.

This definition shall not apply to unintentional quality defects and is without prejudice to the infringement of intellectual property rights.

By Reg-NDR definition of ‘falsified device’ means any device with a false presentation of its identity and/or of its source and/or its t include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

- k. Does the understanding of “victim” under your internal law correspond to that set out in **Article 4, letter (k)**, i.e. “any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8”?

Yes. According to Article 144 of the Criminal Procedure Act “the injured party” (i.e. the victim), denoting either a male or female, means the person whose personal or property rights have been violated or threatened by a criminal offence. Where a direct consequence of the crime is the death of a person, the spouse or the person with whom he or she lived in extra-marital cohabitation, blood relatives in direct line, his or her adopted child or adoptive parent, his or her brothers or sisters and the persons that he or she supported or was obliged to support shall also be considered injured persons pursuant to this Act. “The person with special needs for protection”, which means an injured person with special needs for protection, is the injured person whose personal or property right has been significantly violated by the criminal offence, but who, owing to his or her personal characteristics or vulnerability, is in need of special protection due to the nature, the gravity or circumstances of the crime or the conduct of the accused person or the injured party in pre-trial or criminal proceedings and outside them, in order to protect his or her personal integrity during individual acts in pre-criminal and criminal proceedings

However, when it comes to medical products that are harmful to health, a more serious criminal offence would probably be given – Article 183 of the Criminal Code, which determines a criminal offence of Manufacture and trade in harmful medical products.

## 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.

According to Article 14 of the Constitution of the Republic of Slovenia everyone shall be guaranteed equal human rights and fundamental freedoms irrespective of national origin, race, sex, language, religion, political, or other conviction, material standing, birth, education, social status, disability, or any other personal circumstance.

Following Article 22 of the Constitution everyone shall be guaranteed equal protection of rights in any proceeding before a court and before other state authorities, local community authorities, and bearers of public authority that decide on his rights, duties, or legal interests.

Violation of the right to equality is a criminal offence under Article 131 of the Criminal Code.

Regarding the definition of a victim please also see previous answer to point k.

### 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; Medicinal Products Act (ZZdr-2); Decree on the implementation of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Reg-MDR); Resolution on the national program for the prevention and suppression of crime 2019–2023 (Resolution)

The Act Amending the Criminal Code (KZ-11); Official Gazette of the Republic of Slovenia, No. 186/21:

- amended criminal offence of manufacture and trade in harmful medical products (Article 183 of the Criminal Code),
- new criminal offence of “manufacture and marketing of counterfeit medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements” (new Article 183.a of the Criminal Code).

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;

On the national level Slovenia has adopted Resolution on the national crime prevention and suppression program for the period 2019–2023 (ReNPPZK19–23). In Section 6. 6. 4. 1 entitled ‘Strategy/Program — Prevention of Counterfeiting of Medical Devices and Similar Crimes involving threats to public health key activities/measure, responsible and participating institutions, deadlines for implementation, as well as key performance indicators are listed. In the coming year, the new Resolution will be prepared for the next period. The special working group appointed by the Government of the Republic of Slovenia for the purpose of implementation of the Convention, intends to proceed to prepare a proposal for an action plan to combat counterfeiting of medical products and similar crimes involving threats to public health.

Ministry of Health is responsible for the implementation of the Convention, in cooperation with the Ministry of Justice, the Ministry for internal affairs (Police), Financial Administration of the Republic of Slovenia (Customs), the Supreme State Prosecutor's Office of the Republic of Slovenia and Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

Main fields of action are aimed first at supplementing the legal bases for the effective prevention and prosecution of the criminal acts of counterfeiting medical products and similar criminal acts that threaten public health. For this purpose, Medicrime Convention was signed, ratified and the criminal law was supplemented with provisions that enable the prosecution and sanctioning of the counterfeiting of medical products. A special working group was appointed by the Government of the Republic of Slovenia for the purpose of implementation of the Convention. In the next period, a formal coordination network will be established and national contact points will be appointed. It will be necessary to ensure that the competent authorities are properly integrated for the effective exchange information on falsification of medical products. One of the key activities is the preparation of an action plan.

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.

On the national level Slovenia has adopted Resolution on the national crime prevention and suppression program for the period 2019–2023 (ReNPPZK19–23). In Section 6. 6. 4. 1 entitled 'Strategy/Program — Prevention of Counterfeiting of Medical Devices and Similar Crimes involving threats to public health. One of the key activities of a special working group was appointed by the Government of the Republic of Slovenia for the purpose of implementation of the Convention is the preparation of an action plan.

#### 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**);

Article 145 of the Criminal Procedure Act determines that all state authorities and organizations with public authority are obliged to report criminal offences which are prosecutable *ex officio* if they have been informed of them or if they have been brought to their notice in some other way. In submitting criminal complaints, authorities and organizations must indicate the evidence known to them and undertake measures to preserve the traces of the criminal offence and the objects on which or by means of which the criminal offence was committed, as well as other evidence. Criminal complaint is filed with the competent state prosecutor in writing or orally.

In exercising his or her powers under Criminal Procedure Act, the state prosecutor may according to Article 160.a of the Criminal Procedure Act direct the work of the police and of the competent body within the ministry responsible for defense designated by an Act (Article 158), the work of a joint investigation team (Article 160.b) and the work of other competent state authorities and institutions in the field of taxes, customs, financial operations, securities, protection of competition, prevention of money laundering, prevention of corruption, illicit drugs and inspection supervision (including also the JAZMP and Health Inspectorate), by providing mandatory instructions, expert opinions and motions for the collection of information and the implementation of other measures within their competence for the purpose of uncovering the criminal offence and its perpetrator or collecting information necessary to decide on the criminal prosecution.

In the cases involving complex criminal offences, especially in the field of economy, corruption and organised crime (*but also in cases of complex criminal offences in other areas*) which are the subject of pre-trial proceedings and which require a long-term targeted operation of a number of the above-stated bodies and institutions, the head of the competent state prosecutor's office may, *ex officio* or upon a written motion of the police, establish a specialised investigation team together with the heads of the above-stated particular bodies and institutions. The specialised investigation team is headed and directed by the competent state prosecutor and its members are appointed by the heads of the above-stated bodies and institutions. Upon an order or the prior approval of the state prosecutor, a member of the specialised investigation team may be present or may advise the state prosecutor in the carrying out of particular investigative acts.

In the Republic of Slovenia, we do not have a formal network yet, but we do have an exchange of information at an operational level between institutions (health sector, justice, police, prosecutor's office, customs, etc.). For example - Financial Administration of the Republic of Slovenia (Custom) controls the important of medicines from third countries in accordance with the ZZdr-2. In doing so, Custom

cooperates with JAZMP, which provides Custom with expert support in the implementation of supervision of the import of medical products.

JAZMP cooperates also with the Police in case of a suspicion of a criminal offence according to the article 183 of Criminal code "Manufacturing and supply of harmful products for treatment" or article 183a "Manufacturing and supply of counterfeit medical products, medical products without marketing authorization or medical devices that do not comply with the requirements of the Reg-MDR".

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

According to ZZdr-2 and Reg MDR manufacturers, distributors, pharmacies and retail sales of medicinal products and MD are obliged to immediately notify JAZMP if they obtain information that medicinal product, MD, active ingredient,... are, or are suspected of being, falsified.

- c. Which legislative or other structured measures have been taken to set up or strengthen mechanisms for:

- receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health? (**Article 17, para. 3, letter (a)**);

In the Republic of Slovenia, we do not have a formal network of contact points yet The establishment of this formal network is planned to be defined in the action plan. We do have cooperation at an operational level between institutions. Financial Administration of the Republic of Slovenia (FURS) cooperates with JAZMP in the field of medicines and medical devices. A mutual cooperation agreement has also been concluded for this purpose. In addition, FURS receives notifications from JAZMP, which it exchanges with the competent authorities of other Member States concerning shipments of medicinal products which have been encountered and which are falsified (non-compliant or even dangerous) medicinal products.

- 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)**);

Based on article 4 of Act on Ratification of Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public the Decision on appointment of the working group was issued by the Government of the Republic of Slovenia. The members of the working group, their tasks and the method of operation and decision making are specified in the government decision.

For the criminal procedure part please see answer to question 4.a.

- 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**);

Police, Customs, the Supreme State Prosecutor's Office of the Republic of Slovenia and JAZMP are in charge of co-operation and information exchange in the field of the MEDICRIME Convention. Training is conducted separately by individual services. Training for co-operation and information exchange in the field of the MEDICRIME Convention, which will involve the services of the ministries (health, justice, prosecution), police, customs and JAZMP, will be defined in the strategy and action plan.

For the criminal procedure part please see answer to question 4.a.

### 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**).

JAZMP has been designated as a temporary National Contact Point, but this will need to be re-considered and it is very likely that a new entity would have to be designated, which already has powers for transmitting and receiving confidential information and/or requests for co-operation in connection with the fight against counterfeiting/falsifying of medical products.

- 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.

FURS shall exchange information with the customs authorities of other Member States regarding the findings of consignments of medicinal products. This information is integrated into the Customs Information System in the form of Risk Profiles and, in the event of a hit, the consignment is further scrutinized. Systematically integrate prevention and fight against counterfeiting/falsifying of medical products in assistance programmes is intended to be included in action plan.

## 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.

Yes: In Slovenia all the listed intentional conducts in the box below question 6 are considered criminal offences.

- criminal offence of manufacture and trade in harmful medical products (Article 183 of the Criminal Code),
- criminal offence of "manufacture and trade in counterfeit/falsified medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements" (Article 183.a of the Criminal Code),
- criminal offence of defrauding of customers (Article 232 of the Criminal Code),
- criminal offence of unauthorised use of another's mark or model (Article 233 of the Criminal Code),
- criminal offence of forging of documents (Article 251 of the Criminal Code).

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

Yes, the offences in our internal laws require intentional conduct.

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

The ZZdr-2 in the chapter XIII. Penalty:

1. on Minor offences (Art 191)- on natural person shall be imposed when in importing and entering medicinal products for personal use or the use of its own animal it acts in contravention of Article 16 of this Act.
2. on Major offences (Art 19)2: on legal person shall be imposed if:
  - it places on the market a medicinal product referred to in Article 21 of this Acticle,
  - it fails to notify JAZMP of inadequate quality or suspected falsifying of a medicinal product (Article 23 of this Act),
  - it fails to conclude a contract with the manufacturer in accordance with the second paragraph of Article 27 of this Act,
  - it fails to notify JAZMP and the holder of marketing authorization for falsified or suspected falsified active substances (the second paragraph of Article 100 of this Act),
  - it fails to notify JAZMP of falsified active substances in accordance with the third paragraph of Article 111 of this Act,
  - it fails to notify JAZMP of falsified or suspected falsified active substances (the second paragraph of Article 120 of this Act),
  - a medicinal product for human use does not have a safety feature affixed in accordance with Article 88 of this Act,
  - it fails to provide an anti-tamper device for the protection of outer packaging (the third paragraph of Article 88 of this Act - The manufacturer shall, in addition to the safety feature, also provide a device allowing verification of whether the outer packaging has been tampered with),
  - it fully or partially removes or covers the safety features on the medical product in contravention of the fifth paragraph of Article 88 of this Act (The holder of manufacturing authorization for a medicinal product may remove the safety feature on the medicinal product, either fully or partially, or cover it if : it has previously established that the medicinal product concerned is authentic and that its packaging has not been tampered with, it has replaced the removed or covered safety features with safety features that are equivalent as regards the possibility to verify authenticity, identification and intactness. Such replacement shall be conducted without opening the immediate packaging, the replacement of safety features shall be conducted in compliance with good manufacturing practice for medicinal products, The safety feature does not need not be affixed to radiopharmaceuticals).

The Criminal Code, in the chapter on crimes against human health, also defines the following criminal offences, which are not similar to counterfeit medical products:

- Spreading of contagious diseases (Article 177 of the Criminal Code),
- Failure to render medical assistance (Article 178 of the Criminal Code),
- Negligent medical and alternative medical treatment (Article 179 of the Criminal Code),
- Quackery (Article 180 of the Criminal Code),
- Illegal transplant of human body parts and modification of the human genome (Article 181 of the Criminal Code),
- Trafficking in human body parts, germ cells, blood and blood components (Article 181.a of the Criminal Code),
- Negligent performance of pharmacy service (Article 182 of the Criminal Code),
- Production and trade of food and other products that are harmful to health (Article 184 of the Criminal Code),
- Careless Inspection of meat (Article 185 of the Criminal Code),
- Illicit manufacture and trade in narcotic drugs, illicit substances and procedures in sport and illicit drug precursors (Article 186 of the Criminal Code),
- Facilitating the consumption or use of narcotic drugs or illicit substances or procedures in sport (Article 187 of the Criminal Code).

**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**).

The issue of jurisdiction is governed by Articles 10, 12 and 13 of the Criminal Code of the Republic of Slovenia. Relevant Articles of the Criminal Code:

**Application of the Criminal Code of the Republic of Slovenia to any person who commits a criminal offence in its territory**

**Article 10**

- (1) The Criminal Code of the Republic of Slovenia shall apply to any person who commits a criminal offence in Slovenia's territory.
- (2) The Criminal Code of the Republic of Slovenia shall also apply to anyone who commits a criminal offence on a domestic vessel regardless of its location at the time of the commission of the offence.
- (3) The Criminal Code of the Republic of Slovenia shall also apply to anyone who commits a criminal offence on a domestic civil aircraft in flight or on a domestic military aircraft regardless of its location at the time of the committing of the offence.

**Application of the Criminal Code of the Republic of Slovenia to citizens of the Republic of Slovenia who commit a criminal offence**

**Article 12**

The Criminal Code of the Republic of Slovenia shall be applicable to any citizen of the Republic of Slovenia who commits any criminal offence abroad other than those specified in the preceding Article.

**Application of the Criminal Code of the Republic of Slovenia to foreign citizens who Commit a criminal offence abroad**

**Article 13**

- (1) The Criminal Code of the Republic of Slovenia shall apply to any foreign citizen who has, in a foreign country, committed a criminal offence against the Republic of Slovenia or any of its citizens, even though the offences in question are not covered by Article 11 of this Criminal Code.
- (2) The Criminal Code of the Republic of Slovenia shall also be applicable to any foreign citizen who has, in a foreign country, committed a criminal offence against a third country or any of its citizens if he has been apprehended in the territory of the Republic of Slovenia, but was not extradited to the foreign country. In such cases, the court shall not impose a sentence on the perpetrator heavier than the sentence prescribed by the law of the country, in which the offence was committed.

(3) The Criminal Code of the Republic of Slovenia shall be applicable to anyone who commits any criminal offence abroad which, under relevant international agreement(s) or general legal rules recognised by the international community, is subject to prosecution, regardless of the location where it was committed.

### **Special conditions for the prosecution**

#### **Article 14**

(1) If, in cases referred to in Article 10 and indent 1 of Article 11 of this Criminal Code, the criminal procedure has been initiated or discontinued in a foreign country, the perpetrator may be prosecuted in the Republic of Slovenia only by permission of the Minister of Justice with the notice under which conditions the prosecution shall not violate double jeopardy.

(2) In the cases referred to in Article 12 and paragraphs one and two of Article 13 of this Criminal Code, the perpetrator shall not be prosecuted:

1) if he or she has served the sentence imposed on him or her in a foreign country or if it was decided in accordance with an international agreement that the sentence imposed in a foreign country is to be served in the Republic of Slovenia;

2) if he or she has been acquitted by a foreign court or if his or her sentence has been remitted or the execution of the sentence has fallen under the statute of limitations;

3) if, according to foreign law, the criminal offence concerned may only be prosecuted upon the complaint of the injured party and the latter has not been filed.

(3) In cases under Articles 12 and paragraphs one and two of Article 13 the perpetrator shall be prosecuted only insofar as his conduct constitutes a criminal offence in the country where it was committed.

(4) If, in the case referred to in Article 12 of this Criminal Code, the criminal offence committed against the Republic of Slovenia or a citizen thereof does not constitute a criminal offence under the law of the country where it was committed, the perpetrator of such an offence may be prosecuted only by permission of the Minister of Justice of the Republic of Slovenia.

(5) If, in all other cases except the cases referred to in indent 2 of Article 11, paragraph three of Article 13 and paragraph four of this Article of this Criminal Code, the criminal offence is not punishable in the country where it was committed, the perpetrator may be prosecuted only by permission of the Minister of Justice and with the proviso that, according to the general principles of law recognised by the international community, the offence in question constituted a criminal act at the time it was committed.

(6) In the case referred to in Article 10, the prosecution of a foreign person may be transferred to another country under the conditions provided by the law.

(7) In the cases referred to in paragraph three of Article 13 of this Code, the perpetrator shall be prosecuted only by permission of the Minister of Justice.

### **Question 8: Corporate liability**

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

The Liability of Legal Persons for Criminal Offences Act determines that legal persons may be held liable for all criminal offences from the chapter of the Criminal Code on criminal offences against public health.

Grounds for the liability of a legal person are determined in Article 4 of the Liability of Legal Persons for Criminal Offences Act as follows:

A legal person shall be liable for a criminal offence committed by the perpetrator in the name of, on behalf of or to the benefit of said legal person:

1. if the criminal offence committed entails carrying out an illegal resolution, order or endorsement of its management or supervisory bodies;
2. if its management or supervisory bodies influenced the perpetrator or enabled him to commit the criminal offence;
3. if the perpetrator obtained illegal proceeds from the criminal offence or items that are the result of the criminal offence;
4. if its management or supervisory bodies have omitted obligatory supervision of the legality of the actions of employees subordinate thereto.

Article 5 of the Liability of Legal Persons for Criminal Offences Act defines the limits of the liability of a legal person for a criminal offence:

- (1) Under the conditions referred to in the preceding Article, a legal person shall also be liable for a criminal offence if the perpetrator is not found guilty of the criminal offence or if the act was committed under duress or threat from the legal person.
- (2) The liability of a legal person does not preclude the criminal liability of natural persons or responsible persons for the criminal offence committed.
- (3) A legal person may only be liable for criminal offences committed out of negligence under the conditions referred to in point 4 of Article 4 of this Act. In such case, the legal person may receive a lenient sentence.
- (4) If a legal person has no other body besides the perpetrator who could lead or supervise the perpetrator, the legal person shall be liable for the criminal offence committed within the limits of the perpetrator's guilt.

### 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**);

#### NATURAL PERSONS

**The ZZdr-2** in the chapter XIII. Penalty on Minor offences, Art 191: "A fine of between EUR 800 and EUR 4,000 shall be imposed when in importing and entering medicinal products for personal use or the use of its own animal it acts in contravention of Article 16 of this Act.

#### LEGAL PERSONS

**The ZZdr-2** in the chapter XIII. Penalty on Major offences, Art 192: "A fine of between EUR 8,000 and EUR 120,000 shall be imposed on a legal entity if:

- it places on the market a medicinal product referred to in Article 21 of this Act,
- it fails to notify JAZMP of inadequate quality or suspected falsifying of a medicinal product (Article 23 of this Act),
- it fails to conclude a contract with the manufacturer in accordance with the second paragraph of Article 27 of this Act,
- it fails to notify JAZMP and the holder of marketing authorization for falsified or suspected falsified active substances (the second paragraph of Article 100 of this Act),
- it fails to notify JAZMP of falsified active substances in accordance with the third paragraph of Article 111 of this Act,
- it fails to notify JAZMP of falsified or suspected falsified active substances (the second paragraph of Article 120 of this Act),
- a medicinal product for human use does not have a safety feature affixed in accordance with Article 88 of this Act,
- it fails to provide an anti-tamper device for the protection of outer packaging (the third paragraph of Article 88 of this Act - The manufacturer shall, in addition to the safety feature, also provide a device allowing verification of whether the outer packaging has been tampered

- with),
- it fully or partially removes or covers the safety features on the medical product in contravention of the fifth paragraph of Article 88 of this Act (The holder of manufacturing authorization for a medicinal product may remove the safety feature on the medicinal product, either fully or partially, or cover it if : it has previously established that the medicinal product concerned is authentic and that its packaging has not been tampered with, it has replaced the removed or covered safety features with safety features that are equivalent as regards the possibility to verify authenticity, identification and intactness. Such replacement shall be conducted without opening the immediate packaging, the replacement of safety features shall be conducted in compliance with good manufacturing practice for medicinal products, The safety feature does not need not be affixed to radiopharmaceuticals).

**NATURAL PERSONS:** (*criminal sanctions*)

- imprisonment;
- warning sanctions: suspended sentence

**Criminal offence of manufacture and trade in harmful medical products (Article 183 of the **Criminal Code**):**

- principal criminal offence: imprisonment between one and eight years,
- negligence: imprisonment for not more than one year,
- aggravated criminal offence (a serious or a particularly serious bodily injury or in a corresponding impairment of health of at least one person, or if the offence was committed by a person who abused the trust placed in him or her): imprisonment between one and ten years for the main criminal offence, and for not more than five years for negligence,
- aggravated criminal offence (death of one or more persons): imprisonment between two and fifteen years for the main criminal offence, and between one and ten years for negligence.

**Criminal offence of “manufacture and trade in counterfeit medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements” (Article 183.a of the Criminal Code):**

- principal criminal offence: imprisonment for not more than five years,
- aggravated criminal offence (the offence was committed by a person who abused the trust placed in him or her): imprisonment between one and five years.

**Criminal offence of defrauding of customers (Article 232 of the Criminal Code):**

- a fine or imprisonment for not more than two years.

**Criminal offence of unauthorised use of another’s mark or model (Article 233 of the Criminal Code):**

- imprisonment for not more than three years.

**Criminal offence of forging of documents (Article 251 of the Criminal Code):**

- imprisonment for not more than two years.

**LEGAL PERSONS:** (*criminal sanctions*)

The following sentences may be prescribed for criminal offences committed by legal persons:

- fines;
- the confiscation of property;
- the winding-up of the legal person;
- prohibition of the disposal of securities held by the legal person.

**Fines** that may be prescribed may not be less than EUR 10,000 or more than EUR 1,000,000. In the event a legal person’s criminal offence has caused damage to another’s property, or of a legal person

obtaining illegal proceeds, the highest limit of the fine imposed may be two hundred times the amount of such damage or proceeds.

For criminal offences for which a sentence of up to three years of imprisonment is prescribed for the perpetrator, a fine of up to EUR 500,000, or up to one hundred times the amount of the damage caused or proceeds gained through the criminal offence.

For criminal offences for which a sentence of over three years of imprisonment is prescribed for the perpetrator, a fine of at least EUR 50,000 or up to a maximum of two hundred times the amount of the damage caused or illegal proceeds obtained through the criminal offence.

For criminal offences for which a sentence of five years of imprisonment or a more severe sentence is prescribed for the perpetrator, a sentence of the confiscation of property may be imposed instead of a fine.

**Confiscation of property:** Half, more than half, or the entire property of a legal person's property may be confiscated. The confiscation of property may be imposed for criminal offences that carry a sentence of five years of imprisonment or a more severe sentence. In the case of bankruptcy proceedings resulting from the imposition of a sentence of the confiscation of property, creditors may be repaid from the confiscated property.

**Winding-up of a legal person** may be imposed if the activity of the legal person was entirely or predominantly used to carry out criminal offences. In addition to the winding-up of a legal person, the court may also impose a sentence of the confiscation of property. When sentencing a legal person to winding-up, the court shall propose the initiation of liquidation proceedings. Creditors may be repaid from the property of a legal person sentenced to winding-up.

For criminal offences committed by legal persons, in addition to the safety measure of the confiscation of items in accordance with Article 73 of the Criminal Code, the following may also be imposed as a safety measure:

- publication of the judgement,
- prohibition of the legal person performing a specific commercial activity.

Both natural and legal persons can be deprived of illegal property benefits and objects can be seized.

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

### Question 10: Aggravating Circumstances

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

All of the above, except option d.

According to the General Part of the Criminal Code (Article 49 of the Criminal Code) the perpetrator shall be sentenced for a criminal offence within the limits of the statutory terms provided for such an offence and with respect to the gravity of his or her offence and his or her culpability. In determining the sentence the court shall consider all circumstances that influence the grading of the sentence (mitigating and aggravating circumstances), in particular: the degree of perpetrator's guilt; the motives for which the offence was committed; the intensity of danger or injury caused to the legal value; the circumstances in which the offence was committed; the perpetrator's past behaviour; his or her personal and financial circumstances; his or her conduct after committing the offence and especially whether he or she provided compensation for the damage caused by the criminal offence; and other circumstances relating to the perpetrator's personality and to the expected effect of the punishment on the perpetrators future life in the social environment. In determining the sentence of a perpetrator of a criminal offence after he or she had already been convicted or had served his or her sentence, or after the implementation of his or her sentence had been barred by time, or after his or her sentence has been remitted (recidivism), the court shall pay particular attention to whether the earlier offence is of the same type as the new one, whether both offences were committed for the same motive and to the time which has elapsed since the former conviction or since the serving, withdrawing, remitting or barring of the sentence.

In criminal offence of “manufacture and trade in counterfeit medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements” (Article 183.a of the Criminal Code) only one special aggravating circumstance is determined – i.e. the offence was committed by a person who abused the trust placed in him or her. The principal criminal offence (Whoever manufactures, prepares, produces, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or serves as an agent in the sale or purchase, imports or exports, inputs or outputs or otherwise puts on the market medicinal products, active substances, excipients, medical devices or their parts or accessories or other healing remedies that are counterfeited) exists only if a perpetrator has not committed a more serious criminal offence according to this Code.

**The reason is that Criminal Code also prescribes a criminal offence** of manufacture and trade in harmful medical products (Article 183 of the Criminal Code) with special aggravating circumstances of a serious or a particularly serious bodily injury or in a corresponding impairment of health of at least one person or death of one or more persons (for prescribed sentences please see answer to question 9.a).

### 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**).

The perpetrators of all the criminal offences discussed here are prosecuted *ex officio* according to Criminal Code, so the question is not relevant.

- b. Please indicate the persons, units or services or other formalised or agreed arrangements in charge of criminal investigations in the field of MEDICRIME Convention. Please indicate how specialisation in this field is achieved and how resources are secured for it/them (**Article 16, para. 1, Explanatory Report, paras. 107-110**).
- c. Please describe under which circumstances carrying out financial investigations, the use of covert operations, of controlled delivery and of other special investigative techniques by authorities is allowed in relation to the investigation of the offences established in accordance with the Convention (**Article 16, para. 2**).

Covert surveillance: criminal offences punishable by a sentence of imprisonment of five or more years prescribed by the Criminal Code.

Surveillance of electronic communications including interception and recording, and the control and safeguarding of evidence on all forms of communication transmitted over the electronic communications network; control of letters and other postal items; control of the computer systems of banks or other legal entities engaged in financial or other commercial activities; interception and recording of conversations subject to the approval of at least one person engaged in such conversation: criminal offences punishable by a sentence of imprisonment of eight or more years prescribed by the Criminal Code.

Interception and surveillance in another person's home or premises with the use of technical equipment for recording and, where necessary, by secretly entering home or premises, may exceptionally be ordered for criminal offences punishable by a sentence of imprisonment of eight years or more, such measures may only be ordered if there also exists a serious threat to the lives of people.

The deprivation of liberty of a suspect or the implementation of other measures referred to in this Act may be postponed temporarily in order to disclose a large-scale criminal activity, but only if, and as long as, the lives and health of third parties are not thereby put at risk. The authorisation to postpone these measures shall be granted by the competent state prosecutor upon a properly reasoned motion of the police.

### 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.

According to Article 18.a of the Criminal Procedure Act the police, the state prosecution service, courts and other state authorities, experts, expert witnesses, court and other interpreters and mediators must treat the injured parties, suspects, accused persons and convicts with particular care and act considerately where necessary because of their vulnerability, such as age, health condition, disability, or other similar circumstances.

According to Article 65.a of the Criminal Procedure Act during the first contact, the competent authority in pre-trial or criminal proceedings shall inform the injured party of the method of providing information on:

- free medical, psychological and other assistance and support;
- assistance and measures pursuant to the act governing the prevention of domestic violence;
- protective and other measures for ensuring personal security under this Act and the act governing the protection of witnesses;
- the rights referred to in Article 65 of this Act and the right to free legal aid under the act governing free legal aid;
- the possibilities for compensation for damages under this Act and the act governing compensation to victims of crime;
- payment and reimbursement of the costs incurred by the injured party under Article 92 of this Act;
- the right to interpretation and translation under this Act;

- the contact person of the competent authority with whom he or she can communicate about his or her case;
- any other rights or benefits that may be relevant to the injured party.

The amount and type of information referred to in the preceding paragraph shall depend on the personal characteristics and vulnerability of the injured party, his or her specific needs for protection, the nature, gravity and circumstances of the crime and the stage of pre-trial or criminal proceedings.

The injured party shall have the right to receive information on the state of pre-trial or criminal proceedings and final judgments if he or she makes such a request or if so provided by law (paragraph six of Article 363). The competent authority in pre-trial or criminal proceedings shall inform the injured party of this right and duly record it in such a way that the police, the competent state prosecutor or the judge can become aware of it. Information on the state of pre-trial or criminal proceedings can be provided through websites.

In order to ensure his or her personal security, the injured party may request to be informed of the release or escape of the suspect or accused person from house arrest or from pre-trial detention. He or she shall be informed of this right by the competent authority during the first contact in pre-trial or criminal proceedings, which shall be duly recorded. Such information may be refused if the suspect or accused person could be threatened as a result. The injured party shall be informed of the escape of the suspect or accused person from the house arrest by the police or the court, and of the release of the suspect or accused person from the house arrest by the court. The injured party shall be informed of the escape or the release of the suspect or accused person from the detention by the prison referred to in Article 210 of this Act. The competent authority that received the request of the injured party shall inform the police, the court or the prison referred to in Article 210 of this Act of the request and provide the injured party's contact details. At the request of the injured party, the social work centre shall also be informed.

The injured party may change the decision to receive the information at any time during the pre-trial and criminal proceedings, which shall be duly recorded by the competent authority in such a way that other competent authorities can become aware of it.

- 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**).

Please see answer to question under point a.

- 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)**);

Please see answer to question under point a.

- 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)**)

Please see answer to question under point a.

- 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)**);

Please see answer to question under point a.

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**). Please see answer to question under point a.

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**)

ZZdr-2 regulates the field of medicinal products and the conditions and measures to ensure their quality, safety and efficacy. Reg-MDR sets standards of quality and safety for medical devices.

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

By adoption of Falsified medicines directive (FMD) several measures to prevent the entry of falsified medicinal products into the legal supply chain have been implemented into the national legislation: obligatory safety features for verification of authenticity of a medicinal product, a common EU logo to identify legal online pharmacies, tougher rules on import of active pharmaceutical ingredients and more strict requirements in record-keeping for wholesale distributors.

c. Which measures have been taken to provide for (**Article 18 para. 3 letters a and c, Explanatory Report, para. 114**):

- training of healthcare professionals, providers, law-enforcement (including police and customs authorities), as well as other relevant authorities and civil society?
- the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?

The Centre for Judicial Education (Center) primarily organises training for judges, public prosecutors and public prosecutors. On the initiative and in agreement with our primary target groups, the Centre can also invite other stakeholders (e. g. police, customs, tax offices, etc. ) to participate in the training. When we receive a reasoned proposal of contents together with the proposed experts covering a certain area that needs to be moved, and of course with the prepared financial consequences and, above all, the provided financial means, we prepare or organize the education.

Individual content can be prepared as an independent educational event, or a certain topic can be included in already established and traditional forms, e. g. in judicial schools. In the first case, of course,

the financial burden is significantly higher (which I stress solely because we have recently experienced a concrete reduction of funds by the judicial authorities), the concrete time for the implementation of such training takes from 4 to 6 months, in the second case, both the financial input and the preparation time are reduced, depending on which or what form of already established training a certain topic is placed in.

According to the interinstitutional cooperation between JAZMP and FURS, JAZMP has already carried out training in the field of control and consignments of medicinal products for customs officers.

JAZMP conducted several trainings in the field of medicinal products regulation with an emphasis on measures to prevent the entry of falsified medicines into the legal supply chain for the police and law enforcement authorities.

- 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**);

With the emergence of consignments of medicines received by individuals by post, which were most likely the result of internet purchases, the FURS found that many purchases were made on the right-handed internet store. These were presented as pharmacies, they were in the Slovenian language, although the goods then arrived from third countries (most often from India). An article about this has been prepared and published both on FURS social media and in the news. FURS also participates at the invitation of journalists in the preparation of various articles or broadcasts on the import of medicines.

Activities to raise awareness are for now focused on other official institutions (customs, police, health care inspectorate, market inspectorate). These activities include meetings, symposia, etc. However, on JAZMP's website information on safe online purchases and information on risks when buying medicines online from unauthorized web sites are regularly published, as well as warnings about products that are falsely presented as medicines.