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

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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"?

No. Medicinal products and medical devices are defined separately in the corresponding legislations that in turn follow the definitions provided for in the European Union legislation.

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

The definition of a human and a veterinary medicinal product are provided for separately in their corresponding national legislations [the Medicinal Products for Human Use (Control of Quality, Supply and Prices) and the Veterinary Medicinal Products (Control of Quality, Registration, Marketing, Manufacture, Administration and Use) law. Both legislations transpose the relevant EU Directives and Regulations.

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

Investigational medicinal products are defined in accordance to EU Regulation 536/2014 (Clinical Trials Regulation-CTR).

Medicinal product" means—
(a) any substance or combination of substances, characterized as having therapeutic or preventive properties against human disease, or
(b) any substance or combination of substances that can be used or administered to humans, with the purpose of-
(i) either to restore, correct or modify physiological functions by exerting a pharmacological, immunological, or metabolic action;
(ii) whether a medical diagnosis is made
It doesn't mention anything about use of such products on animals.

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"?

The above definition partially encompasses the current definition in the national (and (EU) legislation (Directive 2001/83/EC). Local legislation defines an active substance as *"Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make 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"?

National legislation for human medicinal products defines an excipient as *"Any constituent of a medicinal product other than the active substance and the packaging material." This is in line with EU Directive 2001/83/EC.*

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"?

No, it is similar but according to Regulation (EU) 2017/745 Article 2(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:
— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

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"?

No, it is similar but according to Regulation (EU) 2017/745 Article 2(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

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

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, labelling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof"?

According to the Pharmaceutical Services, for pharmaceutical products there is no specific or express definition of the term in the national legislation of the Medicinal products of Human Use.

According to Authority for Medical Equipment of Medical Services and Public Health Services, concerning medical devices the understanding of "document" under national law corresponds to that set out in Article 4, letter (h).

i. Does the understanding of "manufacturing" under your internal law correspond to that set out in **Article 4, letter (i)**, i.e.

"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;

There is not express definition of the term in local human medicinal products legislation. However, the term is mentioned in several articles of the said Law. (e.g. article 39 of the Law provides that a manufacturing license is mandatory for both total and partial manufacture of a pharmaceutical product, and for the various processes of dividing up, packaging or presentation).

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;
There is the definition of manufacturer according to Regulation (EU) 2017/745 Article 2(30).
'Manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark;

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"?

There is the definition of manufacturer according to Regulation (EU) 2017/745 Article 2(30).
'Manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark;

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"?

National legislation (also corresponding Directive 2001/83/EC) defines a falsified medicinal product as:

"Any medicinal product with a false representation of:

(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 does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

Covered in Regulation (EU) 2017/745 Article 2(9) under the definition "falsified".

'Falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

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"?

k.

Yes. Covered in Regulation 2017/745 Article 10(16) *(Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.),*
Directive 85/374/EEC Article 6 *(1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation. 2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.)*
and National Law 105(I)/1995 Part II

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.

There is no discrimination. Discrimination prohibited by law “The Anti-Racial and Certain Other Discrimination (Commissioner) Law of 2004 (L. 42(I)/2004), Article 6(1)”
For the purposes of this Law, any treatment or behavior, provision, condition, criterion, or practice, which in the context of activities in the public or in the private sector of activities is specifically governed, prohibited or not permitted, constitutes discrimination prohibited by law , by any law or regulations in force from time to time on what constitutes, according to their provisions, direct or indirect discrimination due to racial or ethnic origin, religion, belief, community, language, color, special needs, age, and sexual orientation.
(2) Discrimination may be discrimination prohibited by law, within the meaning of subsection (1), in respect of any issue, including issues -
(e) social protection, social security, and health care.

There are no express provisions in the national legislation of the medicinal products for human use or medical devices.

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 current legal instrument with regard to human medicinal products is the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law that incorporates the relevant provisions of Directive 2001/83/EC as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.
   For medical devices: Regulations (EU) 2017/745 and 2017/746, National Law 225(I)/2022, and Regulation (EU) 2019/1020.

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;

   As regards the action plans, Cyprus takes part in operation PANGEA (INTERPOL) and operation SHILED (EUROPOL-EMPACT), which are carried out every year and aim to identify counterfeit pharmaceutical products and dismantle criminal organizations

   The Pharmaceutical Services along with the police department and the customs have a close collaboration and exchange information regarding issues concerning pharmaceutical products (either illegal or falsified).

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.

Although there is not a strategy and/or Action Plan, Medical and Public Health Services, perform Market Surveillance activities within the implementation of Regulations (EU) 2017/745 and (EU) 2017/746, National Law 225(I)/2022 and Regulation (EU) 2019/1020.

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**);

Cyprus has implemented a National Medicrime Committee. The Committee consists of representatives from the State General Laboratory, the Legal Services of the Republic, the Police, the Pharmaceutical Services, the Veterinary Services, the Customs Department, and the Medical Devices Authority. This is with a view to create a multidisciplinary team on a national level to address counterfeit medical products.

An excellent cooperation is in place among the Department of Customs and Excise (DC&E) the Police, the Pharmaceutical Services, and all other competent authorities on medicrime. The cooperation between the DC&E and the Cyprus Police is based on an MOU which foresees for the exchange and sharing of relevant information and strategic, tactical and operational intelligence, where appropriate, in particular by facilitating mutual direct or indirect access to databases, development and promotion of best practices, procedures for operational matters with respect to joint actions, joint mobile patrol squads, joint investigation teams, joint intelligence teams, sharing of equipment between services and cooperation on the development, purchasing, deployment and use of technology.

The DC&E is the competent authority with the legal powers to perform controls at the stage of importation and exportation to/ from the Republic of Cyprus. When illegal goods are detected such as drugs substances, controlled pharmaceuticals etc the consignments are seized by the DC&E, suspects are arrested and the cases are delivered to the Cyprus Police for further investigation and prosecution in a court of law.

The DC&E is conducting the investigations in cases, among others, related to the imported and exported medicinal products and medical devices infringing intellectual property rights. For all these cases the seizure is performed by Customs in cooperation with the Pharmaceutical Services and Medical Services, in order to provide their expertise and administrative assistance.

Concerning medical devices, are stopped at the country's entry points and the responsible competent authority is called for an opinion. The competent authority may also instruct customs on specific products suspected of being counterfeit.

There is cooperation between the Police, Pharmaceutical Services, Health Services, Customs Authorities, and other competent authorities to combat counterfeit products. There are certain **members** of the Anti-Intellectual Property Offenses & Illegal Betting Branch as points of contact for communicating with the relevant authorities, cooperating, exchanging information, and conducting operations to combat such offences.

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**)

Information is obtained from economic operators (manufacturers, authorised representatives, importers, and distributors) on possible products that may be on the market and may be counterfeit

The DC&E cooperates with right holders, in the framework of imported and exported goods when medicines and medical devices violate intellectual property rights.

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)**);

1.A Memorandum of Understanding (MOU) between DC&E and Police
2.Several notices issued by other governmental authorities are conveyed to the personnel with instructions on the procedures that must be followed.
3.Regulations (EU) 2017/745 and (EU) 2017/746 Articles 11(3), 13(7) and 14(4), National Law 225(I)/2022 Article 17 and Regulation (EU)2019/1020.

- 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)**);

1.A MOU between DC&E and Police
2.Several notices issued by other governmental authorities are conveyed to the personnel with instructions on the procedures that have to be followed.
3. Regulations (EU) 2017/745 and (EU) 2017/746 Articles 10(14), 11(3), 13(7) and 14(4), National Law 225(I)/2022 Article 17 and Regulation (EU)2019/1020.

4. There is a memorandum of cooperation with the pharmaceutical and health services regarding the exchange of information, operational cooperation, protocol of actions regarding products that contain the substances CBD, THC, HHC.

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**);

- State General Laboratory: Ms Theodora Papamichael and Ms Maria Afxentiou
- Legal Service: Ms. Dena Maria Ergatoudi
- Customs Department: Ms. Niki Protopapa
- Police: Senior Sergeant 1632 Grigoris Agapiou and Sergeant 2421 Efraim Olympios
- Authority for Medical Equipment of Medical Services and Public Health Services: Ms. Andri Stylianou and Mr. Andreas Loullis
- Pharmaceutical Services: Ms. Galateia Theofanous and Mr. Alexandros Zachariades
- Veterinary Services: Mr. Christodoulos Pipis and Mr. Marios Genakritis

There is no previous training as far as MEDICRIME is concerned so far.

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**).

For Medical Equipment - Cyprus Medical Devices Authority
For the Police - Sergeant 1587 Pantelakis Andreou is appointed as the point of contact for the Police, who is in charge of the Office for Combating Intellectual Crime & Illegal Gambling. Additionally, there are some other members of the Branch designated as substitutes.

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.

No

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.

Points 6, 7 and 8 are considered criminal offence and national regulations for medical devices are being prepared within the framework of harmonizing national law with regulations. There isn't any mention in the legislation for medical devices for points 5 and 9.

Article 5 , Point 1: Pursuant to the provisions of the Medicinal Products for Human use (Control of Quality, Supply and Prices) Law, "any person who in person or through an employee, manufactures, distributes, brokers, imports and exports a falsified medicinal product including the sale at a distance of falsified medicinal products to the public via the services provided by the information society, is guilty of an offence and is subject to imprisonment of no more than 5 years and/or a fine not exceeding 85,000 Euro.

Article 6 , Point 1: Pursuant to the provisions of the Medicinal Products for Human use (Control of Quality, Supply and Prices) Law, "any person who in person or through an employee, manufactures, distributes, brokers, imports and exports a falsified medicinal product including the sale at a distance of falsified medicinal products to the public via the services provided by the information society, is guilty of an offence and is subject to imprisonment of no more than 5 years and/or a fine not exceeding 85,000 Euro.

According to the Police:

Construction of false inscriptions. The Medicines for Human Use (Control of Quality, Supply and Prices) Law of 2001 (70(I)/2001) Article 99,

- Supply, supply proposal and trading of counterfeits. The Medicines for Human Use (Control of Quality, Supply and Prices) Law of 2001 (70(I)/2001) Article 99

- Falsification of documents. The Criminal Code Law, Chapter 154, Articles 331, 333, 334, 335

- Aiding or abetting and attempting. The Criminal Code Law, Chapter 154, Articles 20,366,371

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

According to Articles 13(7) and 14(4) of the Regulation (EU) 2014/745, importers and distributors shall inform competent authorities when they consider or have reason to believe that the device presents a serious risk.

If they know the device presents a serious risk and make it available on the market then it is an offence. But if they don't know it presents a serious risk and make it available on the market then it is not an offence (the offense is the guilty intention).

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;

No

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 legislation applies to all the points mentioned in article 10. There is Chapter 154 article 5 where the application inside and outside the Territorial Sovereignty is also mentioned.

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.

Pursuant to the provisions of the Medicines for Human Use (Control of Quality, Supply and Prices) Law 2001 (70(I)/2001), "When an offence pursuant to the present Law is committed by a legal person or from a person acting on behalf of a legal person and it is proven that it has been committed with the consent, complicity or approval or has been aided by the proven negligence of a consultant, director, secretary or any other natural person, seemingly acting on such capacity, the natural person is also guilty of the offence."

This applies to offences committed in relation to falsified medicinal products intended for human use.

In National Law 225(I) Article 29(e) regarding medical devices, it is mentioned that a person may be held liable for an offense without specifying whether it also covers legal persons.

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**);

National Law 225(I) Article 30.

National regulations for medical devices are being prepared within the framework of harmonizing national law 225(I) with Regulations (EU) 2017/745 and 2017/746 providing sanctions as follows: "Importers and distributors who place falsified products on the market commit an offense and are subject, upon first conviction, to imprisonment for up to two years or a fine not exceeding one hundred thousand euros, or both penalties, and upon second or subsequent conviction, to imprisonment for up to 3 years or a fine not exceeding one hundred fifty thousand euros, or both penalties."

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**).

The some as point 9a.

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**).

In regards to medical devices legislation, there is no provision that covers this.

Question 11: Investigations and criminal measures

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

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

Incidents concerning the criminal aspect of the Medicines for Human Use (Control of Quality, Supply and Prices) Law of 2001 (70(I)/2001) are investigated by the Police (from Police Stations or the Crime Investigation Department) with the assistance of the members of the Office for Combating Intellectual Property Crime & Illegal Gambling. There is no special training or specialization of the members who investigate such cases.

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**).

Domestic legislation allows for financial investigations, covert operations and controlled deliveries. This of course depends on the circumstances of each case. As far as financial investigations are concerned, such a possibility derives from the "Law on the Prevention and Combating of Money Laundering from Illegal Activities of 2007 (188(I)/2007)" and from the "Law on Criminal Procedure (CHAP.155), article 6(I) while as far as covert operations and controlled deliveries are concerned, the possibility derives from the "Regulation of Certain Investigative Powers (Undercover Police) Law of 2017 (L. 189(I)/2017)".

Question 12: Measures of protection for the victim

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

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

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

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

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

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

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

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

Obligations of involved agencies and non-governmental organizations

4.(1) Each involved agency and/or non-governmental organization, when implementing the provisions of this Law-

(a) Recognizes and treats the victim with respect, sensitivity, individualized, professional and non-discriminatory approach, in every contact of the victim with the victim support services or the prosecuting and judicial authorities acting in the context of the criminal procedure;

(b) ensure the enjoyment of measures to protect and promote the rights of victims, without discrimination on any grounds including sex, race, colour, language, disability, religion, political or other conscience, national or social origin, membership of a national minority, property, birth, or any other status of the victim;

(c) where the victim is a child, ensure the best interests of the child, which is assessed on an individual basis, taking due account of the child's age, maturity, views, needs and concerns;

Provided that the child and the exerciser of parental responsibility or his other legal representative, if any, are informed of any measures or rights that specifically concern the child;

(d) ensure that victims with disabilities can fully enjoy their rights on an equal basis with others, by facilitating, inter alia, their access to criminal proceedings and their access to information;

(e) in case the victim is a person with a disability, who has difficulty or is unable to defend himself, ensure the best interest of that person, which is assessed on an individual basis, taking due account of his age, his disability, his difficulties and limitations, his views, his needs and his concerns;

Provided that this person and/or his legal representative, if any, are informed of any measures or rights that specifically concern this person.

(f) take account of the needs of victims of terrorism and take the necessary measures to ensure their dignity and safety;

(g) ensure that a person who has experienced gender-based violence is provided with special support and protection due to the high risk of secondary and repeated victimization, intimidation and retaliation associated with such violence;

(h) in case the violence is committed in the context of a close relationship, provide special protection measures to the victim, especially in the case of a woman who is dependent on the perpetrator financially, socially or in terms of her right of residence.

51(I)/2016
PART II PROVISION OF INFORMATION AND SUPPORT
Victims' right to understand and be understood
5. (1) The Police shall take appropriate measures to help the victim to understand and be understood, from the first contact and in any further necessary communication in the context of criminal proceedings, as well as to understand the information provided by them.

(2) The Police, in communicating with the victim, use simple and understandable language, orally or in writing, considering the personal characteristics of the victim, including any disability, which may affect the victim's ability to understand or be understood:

Provided that communication, oral or written, is in a form accessible to persons with disabilities, including, where necessary, Braille or sign language.

(3) During the first contact with the Police, the victim may be accompanied by a person of his choice, when, due to the consequences of the criminal act, he needs help to understand or to be understood, unless this is against the interests of the victim or impairs the course of the process:

Provided that, in case the victim is a person with a disability, he may be accompanied by a person of his choice throughout the investigation of the case.

51(I)/2016
Right to receive information from the first contact with the service involved
6. (1) Each agency involved shall, upon first contact with the victim, provide without undue delay and in a language the victim understands, including Braille and sign language, the following information:

(a) The type of support the victim can receive and from whom, including, where applicable, basic information about access to medical care, any special support, including psychological help, and alternative accommodation;

(b) the procedures for reporting a criminal offense and the role of the victim in those procedures;

(c) the manner and conditions of providing protection, including protection measures;

(d) the manner and conditions under which the victim may receive compensation;

(e) the manner and conditions under which the victim is entitled to interpretation and translation services;

(f) if the victim resides in a Member State outside the Republic, where the criminal act was committed, and the first contact with the agency involved takes place in the

Republic, any special measures, procedures, or arrangements available to him to protect his interests in the Republic;

(g) the available complaint procedures if the victim's rights are not respected by the agency involved;

(h) the contact details of the relevant officer of the agency involved, for the purposes of communication about his case; and

(i) the method and conditions for reimbursement of the costs of his participation in the criminal procedure.

(2) (a) The extent and/or degree of detail of the information referred to in subsection (1) may vary, depending on the special needs and personal situation of the victim and the type and/or nature of the criminal act.

(b) Each involved agency may provide additional information at a later stage, depending on the needs of the victim and the usefulness of this information at each stage of the process.

(c) Each involved agency or non-governmental organization shall provide the information referred to in subsection (1) and in any case where it judges or has reasonable suspicions to believe that any person may be a victim under the provisions of this Law.

51(I)/2016
Right of victims when filing a complaint
7. (1) Upon submission of a complaint by the victim, the Police shall provide the victim with an evidentiary document for each official complaint submitted, in which the basic elements of the relevant criminal act are mentioned.

(2) In the event that a victim wishes to report a criminal act and does not understand or speak the official language of the Republic, he submits his report in a language he understands or receives the necessary language assistance.

(3) In the event that a victim does not understand or speak the official language of the Republic, he shall receive, upon request, a free translation of the documentary evidence of his complaint, in a language he understands:

Provided that, if a victim presents a visual sensory disability, the document will be converted into Braille format free of charge.

51(I)/2016
Right of victims to receive information about their case
8. (1) The Police shall, without undue delay, inform the victim of his right to receive, upon request, the following information regarding the criminal proceedings initiated following the reporting of the criminal act, which was committed against him:

(a) Any decision not to proceed with or terminate the investigation or prosecution of the offender;

(b) the time and place of the trial and the nature of the charges against the offender;

(c) any final judgment entered at trial;

(d) information that allows the victim to know the course of the criminal proceedings, except in exceptional cases in which the orderly conduct of the case may be disturbed by this notification, following a decision of the Attorney General of the Republic.

(2) The information provided under paragraphs (a) and (c) of subsection (1) shall include the reasons or a summary of the reasons for the decision referred to in said paragraphs.

(3) The Police, at least in cases where there is a possible or established risk of harm to the victim, without delay, informs the victim of his right to be informed about-

(a) the date of release from prison or the escape of the remand, accused or convicted of an offense involving the victim,

(b) any measures decided for the protection of the victim, in case of release or escape of the remand, accused, or convicted for a criminal act concerning the victim:

Provided that, the information provided for in this subsection is not provided in the event that-

(i) there is an established risk of harm to the perpetrator due to the disclosure of the information, or

(ii) the victim has requested in writing not to receive this information:

It is further provided that the Department of Prisons provides the information provided in paragraphs (a) and (b) to the Police, without undue delay.

51(I)/201636(I)/2022
Right of interpretation and translation
9. (1) The Police and/or the Court shall ensure that interpretation is provided free of charge to a victim who does not understand or speak the language of the criminal proceedings, upon request, at least during each examination as a witness in the context of the criminal proceedings before investigative and judicial authorities, including police investigations:

It is understood that a victim with an auditory sensory disability is provided with free sign language interpretation.

(2) Without prejudice to the rights of the defence and in accordance with the rules of discretion of the Court, the use of communication technology such as video conferencing, telephone or the Internet is permitted, unless the personal presence of the interpreter is necessary for the victim to understand the procedure.

(3) The Police and/or the Court shall provide free of charge to the victim who participates as a witness in a criminal proceeding and does not understand or speak the language of the relevant criminal proceeding, if the victim so requests, translations of the information that is essential for the exercise of the of his rights during the criminal procedure in a language he understands, to the extent that this information is made available to the victim:

Provided that, in case the victim is a person with a visual sensory disability, this information is also provided in Braille format.

(4) The information translated pursuant to the provisions of subsection (3) shall include at least every decision on the termination of the criminal proceedings concerning the criminal act, which was committed against the victim and, upon his request, the reasons, or a summary of the reasons for said decision.

(5) A victim, who is entitled to be informed of the time and place of the trial, in accordance with the provisions of paragraph (b) of subsection (1) of article 8 and who does not understand the language used by the Court or the Police, as applicable, receives, upon request, a translation of the information to which he is entitled.

(6) The victim may submit a reasoned request to the Court or the Police, as applicable, for the classification of a document as essential.
It is understood that there is no right to claim a translation of a text excerpt of essential documents, which do not contribute to the active participation of the victim in the criminal procedure.

(7) Subject to the provisions of subsections (1), (3) and (4), the written translation may be replaced by an oral translation or oral summary of the material documents, provided that such oral translation or oral summary does not affect the conduct of a fair trial.

(8) (a) The victim is entitled to submit an oral objection to the Court -

(i) For his decision, by which he considers that it is not necessary to provide a translation of a document and/or to convert a document into Braille and/or to provide an interpretation and/or to provide an interpretation in sign language, in accordance with this Law,

(ii) that any document translation and/or interpretation provided pursuant to this Law is insufficient to ensure a fair trial.

(b) The Court shall decide without delay on an objection submitted pursuant to paragraph (a), recording in the minutes of the proceedings the oral objection and its own reasoned decision on the objection.

(c) In the event that the Court accepts an objection submitted pursuant to the provisions of paragraph (a), it shall take appropriate measures to provide translation and/or interpretation, as required in accordance with the provisions of this article.

(9) The interpretation and translation, as well as the possible examination of a violation of a decision not to provide interpretation or translation pursuant to the provisions of this article shall not unreasonably delay the criminal proceedings.

51(I)/2016
Right of access to victim support services

10. (1) After the victim's complaint, any involved agency or non-governmental organization, in case it judges and/or has reasonable suspicions to believe that any person may be a victim under the provisions of this Law, may inform the Social Welfare Services, which provide free and confidential victim support services as needed before, during and for a reasonable period after the criminal proceedings, including services provided by non-governmental organizations that may provide special support .

(2) The following persons have access to the services provided for in subsection (1):

(a) The victim, regardless of the formal complaint of a criminal offense and depending on his needs; and

(b) the members of the victim's family, depending on their needs and the severity of the damage they suffered due to the criminal act committed against the victim.

(3) The competent authority for the coordination and supervision of all involved services for the effective implementation of the provisions of this article is the Social Welfare Services.

(4) The Social Welfare Services may delegate their responsibilities pursuant to subsection (1) to a non-governmental organization, which is dedicated to the protection and assistance of victims, and/or to local self-government authorities, based on a cooperation protocol or a special agreement between there.

51(I)/2016
Support from victim support services
11. (1) The Social Welfare Services shall ensure that the victim receives -

(a) Information, advice, and support regarding the exercise of his rights, including but not limited to -

(i) the enforceable right to damages against the offender, for the criminal offenses committed against him; and

(ii) his role in the criminal proceedings, including his preparation for participation in the trial as a witness in cooperation with the Mental Health Services and the prosecuting authorities;

(b) information about or direct referral to existing special support services;

(c) emotional support and, if there is a need for psychological support, referral to the Mental Health Services and/or the Educational Psychology Service of the Ministry of Education and Culture in case the victim is a student,

(d) networking with other services, such as psychological support services, housing, financial support and medical services.

(2) Social Welfare Services-

(a) In case the victim is a student, in collaboration with the Mental Health Services and the Educational Psychology Service of the Ministry of Education and Culture, examine with particular care the special needs of the victim who suffered significant damage due to the seriousness of the offense and ensure the provision of targeted and comprehensive support, including post-traumatic and counselling support, when this is a victim with special needs, such as a victim of sexual exploitation or sexual abuse or gender-based or intimate partner violence, or when the victim is a person with a disability;

(b) arrange for the establishment of shelters for the accommodation of the victims, pursuant to the provisions of the Regulations issued in accordance with the provisions of article 25;

(c) inspect the registration and operation of shelters pursuant to the provisions of the Regulations issued in accordance with the provisions of article 25.

51(I)/2016
PART III PARTICIPATION IN CRIMINAL PROCEEDINGS
Right to be heard
12. (1) Every victim may participate as a witness in the criminal proceedings and present evidence in accordance with the criminal procedural rules and the rules of the law of evidence applicable in the Republic.

(2) The prosecuting authorities as well as any other agency involved shall take appropriate measures so that, in coordination with each other, they ensure that the victim is examined and interrogated only insofar as this is necessary for the purposes of the criminal procedure and in accordance with the criminal procedural rules applicable in the Republic.

51(I)/2016
Right to reimbursement of expenses
13. The Republic compensates the victim who cooperates with the prosecuting authorities as a witness in criminal proceedings for any costs to which he is subject, due to his participation in the criminal proceedings.

51(I)/2016
Right of return of assets
14. The Court, after the issuance of its decision, may issue a decree by which it orders that the victim's returnable assets, which were seized during the criminal proceedings, be returned to the victim without delay, unless their seizure is required for the purposes of criminal proceedings.

51(I)/2016
Victims' right to compensation
15. (1) Without prejudice to any other remedy or remedy provided under the provisions of any other law or regulations, any person who is a victim within the meaning of this Law shall have an enforceable right to damages against the perpetrator, for any criminal act committed against and the perpetrator bears a corresponding civil liability for the payment of special and general damages to the victim.

(2) In the event of the death of the victim, the members of the victim's family are entitled to compensation, as specified in article 2.

51(I)/2016
Right of victims residing in another Member State
16. (1) In the event that the victim resides in another member state, the prosecuting authorities, to reduce the difficulties arising regarding the organization of the procedure:

(a) Take a statement from the victim, immediately after the offense is reported;

(b) use as much as possible the provisions on videoconferencing and telephone conferencing, in accordance with the provisions of the Convention drawn up by the Council based on Article 34 of the Treaty on European Union, on Mutual Assistance in Criminal Matters between Member States of the European Union and the Protocol of the (Sanction) Law, which concern the hearing of victims residing abroad.

(2) In the event that the victim of a criminal act committed in the Republic resides in another Member State, he may submit his complaint to the competent authorities of the Member State of his residence, if he is unable to do so in the Republic or, in the case of a felony, if he does not wish to do so in the Republic.

(3) In the event that the victim submits a complaint to the prosecuting authorities of the Republic for the commission of a criminal act committed in another member state, the prosecuting authorities of the Republic, if the competence to initiate proceedings has

not been exercised, forward the complaint to the competent authority without delay of the Member State where the offense was committed.

51(I)/2016
PART IV PROTECTION OF VICTIMS AND IDENTIFICATION OF VICTIMS WITH SPECIAL PROTECTION NEEDS
Right to protection
(1) A victim who wishes to cooperate with the prosecuting authorities, in the context of the criminal procedure, is considered a witness in need of assistance within the meaning of the Witness Protection Law and, if this is necessary, is included in the Witness Protection and Associates of Justice Plan.

(2) In compliance with the provisions of the Witness Protection Law and without prejudice to the rights of the defence, the Court, individually assessing the personal situation of the victim, ensures that the victim receives special treatment aimed at preventing his subsequent victimization, from questions about his private life and from unnecessary questions as well as from the risks of mental, emotional, or psychological harm, and to protect the dignity of the victim.

(3) The prosecuting authorities shall ensure, if deemed necessary under the circumstances, that effective and appropriate protection is provided to the victim against possible revenge or intimidation, during and after the investigation and prosecution of the perpetrator.

(4) In case the victim is a child, the prosecuting authorities -

(a) Ensure that the investigation or prosecution does not depend on the submission of a complaint by the victim or his representative and that the criminal proceedings may continue even if that person withdraws his testimony;

(b) continue the prosecution even after the victim has reached the age of majority.

51(I)/2016
Right to avoid contact between the victim and the perpetrator
18. The Police shall ensure the creation of the necessary conditions to avoid contact between the victim and, if necessary, the members of his family and the offender in the premises of the Court, unless such contact is required in the context of the criminal proceedings.

51(I)/2016
Right to protection of victims during criminal investigation
19. Without prejudice to the rights of the defence and in accordance with the rules of discretion of the court, the prosecuting authorities during the criminal investigation shall ensure the following:

(a) The interview of the victim is carried out without undue delay after the offense has been reported to the Police;

(b) the number of interviews of the victim is kept to a minimum and interviews are conducted only when strictly necessary for the purposes of the criminal investigation;

(c) the victim may be accompanied by his legal representative and a person of his choice, unless a reasoned decision to the contrary has been taken regarding one or both persons;

(d) medical examinations are kept to a minimum and are carried out only when strictly necessary for the purposes of the criminal proceedings.

51(I)/2016
Right to privacy
20. (1) During the criminal proceedings, the prosecuting authorities take appropriate measures to protect the privacy of the victim, including his personal characteristics which are considered during the individual assessment provided for in Article 21 and his image victim and his family members.

(2) The prosecuting authorities may take any legal measure to avoid the dissemination of any information that may lead to the identification of a child victim.

(3) The privacy and identity of the victim is protected by every agency involved and the processing of his personal data is always done in accordance with the provisions of the Processing of Personal Data (Protection of the Individual) Law.

51(I)/2016
Individual victim assessment to determine special protection needs
21. (1) The Police conducts a timely individual assessment of the victim, with the aim of -

(a) The determination of his special protection needs; and

(b) deciding whether and to what extent the victim may benefit from special measures during the criminal proceedings, as provided for in articles 22 and 23 due to a particular risk of suffering secondary and repeated victimization, intimidation, and retaliation.

(2) Depending on the result of the assessment referred to in subsection (1), the Police cooperates, where necessary, with the Social Welfare Services, the Mental Health Services, and the Medical Services for further assessment of the victim's needs in accordance with the provisions of article 11.

(3) The following elements are mainly considered in the individual assessment:

(a) The personal characteristics of the victim;

(b) the type and/or nature of the crime; and

(c) the circumstances of the crime.

(4) In the context of the individual assessment, the prosecuting authorities in cooperation with the Social Welfare Services, the Mental Health Services and the Medical Services, pay special attention to victims who have suffered significant harm due to the seriousness of the crime, to victims of crime due to prejudice or discrimination, which could, in particular, be related to their personal characteristics, and to victims who are particularly vulnerable due to their relationship with the perpetrator or their dependence on him, in particular victims of terrorism, organized crime, human trafficking , gender-based violence, intimate partner violence, sexual violence or exploitation or hate crime and to victims with disabilities.

(5) For the purposes of this Law, when the victim is a child, it is presumed that the child victim has special protection needs and to determine whether and to what extent he or she would benefit from the special measures provided for in articles 22 and 23, the child victim is submitted to an individual evaluation in accordance with the provisions of subsection (1).

(6) The extent of the individual assessment may be adjusted, depending on the seriousness of the crime and the degree of obvious damage suffered by the victim.

(7) The individual assessment is carried out with the close participation of the victim and during its execution his wishes are considered, including his wish not to take the special measures provided for in articles 22 and 23.

(8) If the circumstances underlying an individual assessment have changed significantly, the agencies involved shall take all appropriate measures so that the individual assessment is updated throughout the criminal proceedings.

51(I)/2016
Right to protection of victims with special protection needs during criminal proceedings
22. (1) Without prejudice to the rights of the defence and in accordance with the rules of the Court's discretion, the victim with special protection needs who benefits from special measures, which are decided after carrying out an individual assessment in accordance with the provisions of subsection (1) of article 21 may benefit from the measures provided for in subsections (2) and (3) of this article:

Provided that, a special measure decided after an individual assessment is not applied, if operational or practical limitations make this impossible or if there is an urgent need to examine the victim and the failure to examine him may harm the victim or another person or affect the course of the process.

(2) During the criminal investigation, a victim who is recognized as a victim with special protection needs in accordance with the provisions of subsection (1) of article 21, has the following measures at his disposal:

(a) Each interview of the victim shall be conducted in a place specially designed or adapted for that purpose;

(b) each interview of the victim is conducted by or with the assistance of a professional trained for the purpose;

(c) each interview of the victim is conducted by the same person, unless this would be contrary to the proper administration of justice; and

(d) every interview of a victim of sexual violence, gender-based violence or violence in the context of intimate relationships, is conducted by a person of the same gender as the victim, if the victim so wishes, if the course of criminal proceedings is not affected.

(3) During the proceedings before the Court, a victim who is recognized as a victim with special protection needs in accordance with the provisions of subsection (1) of article 21 has at his disposal the following:

(a) Measures to avoid any visual contact between the victim and the perpetrator, including during the testimony, using appropriate means, such as communication technology;

(b) measures to allow the victim to participate in the hearing in the courtroom without being present, by using appropriate communication technology;

(c) measures to avoid unnecessary questions about the victim's private life unrelated to the offence; and

(d) measures enabling the hearing to be held in camera.

h) Domestic legislation in accordance with the above Law, provides the possibility for governmental and non-governmental organizations to help and support victims, with their consent, during criminal proceedings.

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 legal instrument for human medicinal products is the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law, 2001 (70(I)/2001).

Concerning medical devices, safety requirements are covered by Regulations (EU) 2017/745 and 2017/746 Annex I.

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

The legal instrument for human medicinal products is the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law, 2001 (70(I)/2001).

Safe distribution of medical devices is covered by the Regulation (EU) 2017/745 and 2017/746 Article 14.

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?

According to Medical Devices and Healthcare Services, no measures have been taken for healthcare professionals.

For custom authorities there was a training on basic requirements of Regulations 20147/745 and 2017/746.

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

According to Medical Devices and Healthcare Services, no measures have been taken

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**);

No policies or strategies have been implemented yet.