The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

GENERAL OVERVIEW QUESTIONNAIRE ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

As adopted by the Bureau of the MEDICRIME Committee on 7 July 2020

Replies should be addressed to the MEDICRIME Committee Secretariat by **23 September 2020** (**medicrime@coe.int**)

Document prepared by the MEDICRIME Committee Secretariat
Directorate General I – Human Rights and Rule of Law

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I. INTRODUCTION

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health [1] (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force in January 2016, requires criminalisation of the manufacturing of counterfeit medical products, of the supplying, offering to supply and trafficking in counterfeit medical products, of the falsification of documents and of the unauthorised manufacturing or unauthorised supplying of medicinal products and of the placing on the market of medical devices which do not comply with conformity requirements. The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.

2. The Committee of the Parties to the Convention (also known as the "MEDICRIME Committee"), established to monitor whether Parties effectively implement the Convention, decided that:

> 1. *Following ratification and within six months from the entry into force of the MEDICRIME Convention in respect of the Party concerned, every Party to the Convention shall be required to reply to a questionnaire aimed at providing the MEDICRIME Committee with a general overview of its legislative practice, institutional framework and policies for the implementation of the Convention at the national, regional and local levels. Thereafter, the Parties should regularly inform the MEDICRIME Committee of any substantial changes to the situation described in their replies to the general overview questionnaire.*
>
> 2. *States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.*
>
> 3. *The secretariat shall compile the replies received and make them public on the Committee's website[2].*

3. In accordance with Rule 26 of the Committee's Rules of Procedure:

> *" (…)*
> 2. *The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*
>
> 3. *Parties shall coordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The*

[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.

replies to the questionnaire shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

4. *The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time-limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.*

5. *The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the Bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."*

4. The purpose of this general questionnaire is to collect information to provide the MEDICRIME Committee with an overview of the situation, which will constitute the general framework within which it will assess replies by Parties to the thematic questionnaire for the first monitoring round (see Rule 24 of the MEDICRIME Committee's Rules of Procedure).

II. PRELIMINARY REMARKS

5. The provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without necessarily following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.

6. Parties will be invited to update their replies to this general questionnaire when they will receive the next thematic questionnaire. Responses to a thematic questionnaire should therefore be interrelated and combined with the responses provided in the context of this questionnaire.

7. Parties are kindly requested to:

- specify which state body/agency was responsible for collecting the replies to this questionnaire and which state bodies/agencies (and, at the discretion of the country, where relevant, civil society and external contributors) contributed to responding to this questionnaire;
  Ministry of Justice was responsible for collecting the replies to this questionnaire. The replies were submitted by the Ministry of Interior, Ministry of Human Capacities, Ministry of Justice, Ministry of Foreign Affairs and Trade, National

Institute of Pharmacy and Nutrition (hereinafter: OGYÉI) and National Office for the Judiciary.

- 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;
  https://njt.hu/translated/doc/J2012T0100P_20200716_FIN.PDF
  The texts of other laws are attached or included in the replies.

- 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"?
   The Act C of 2012 on the Criminal Code (hereinafter: CC) establishes two separate offence descriptions regarding the counterfeiting of medicinal products [Section 185/A of CC] and the counterfeiting of medical products [Section 186 of CC]. These two definitions reading together comply with the term of the Convention.

   According to Section 186 (5)(a) of CC, **medical product** means a medical device, in vitro diagnostic medical device, and investigational medicinal product.

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;

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

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;
The definition of medicinal product is completely harmonized with the definition of the Convention.

Section 1 point 1 of the Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (hereinafter: Act XCV of 2005) establishes the term of **medicinal product**: it shall mean any substance or combination of substances presented for treating or preventing diseases in human beings or any substance or combination of substances which may be used in, or directly applied to, the human body, 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.

Point 3 of the Annex to the Act No XLVI of 2008 on food chain and its control determines the definition of **medicines for veterinary use**. It shall mean any substance or combination of substances presented for treating or preventing diseases in animals or any substance or combination of substances which may be used in, or directly applied to, the animal body, 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"?
Section 1 point 6 of the Act XCV of 2005 states that **investigational medicinal product** shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products that already have a marketing authorization but are used or assembled (formulated or packaged) in clinical trials in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form of the medicinal product in question.

Moreover, Section 185/A (8)(b) of CC widens the definition and determines that a medicinal product or veterinary medicinal product not licensed in Hungary also means a product where the active medicinal substance is used in violation of the legislative provisions pertaining to the composition of that product. A medicinal product without a marketing authorisation for Hungary shall be considered a licensed medicinal product if it is subjected to an activity specified in paragraph (1)(b) or (d) that may be pursued in a lawful manner after obtaining an authority licence or making a notification as required by law.

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"?
Section 1 point 38 of the Act XCV of 2005 determines the term of **active substance**: it shall mean 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"?
Section 1 point 39 of the Act XCV of 2005 establishes the definition of **excipient**: it shall mean any constituent of a medicinal product other than the active substance and the packaging material.

e. Does the understanding of "medical devices" under your internal law correspond to that set out in **Article 4, letter (e)**, i.e. "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
   iii. investigation, replacement or modification of the anatomy or of a physiological process;
   iv. control of conception;

   and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"?
Section 3(h) of the Act CLIV of 1997 on health (hereinafter: Act CLIV of 1997) determines the term of **medical devices**: 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 or for use on a sample of human origin.

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"?
The definition of **accessory** is determined by Section 4(1) of Decree 4/2009 (III. 17.) of the Ministry of Health on medical device. It is identical with the term set out in Convention Article 4(f).

Pursuant to this rule, for the purposes of this Decree, a product not covered by Section 2(1), which itself is not a medical device but according to the expressed intention of the manufacturer is designated to be used together with a medical device with the aim of facilitating the initial intended use of the medical device (hereinafter the term of device covers the term of accessory as well).

Furthermore, it should be noted, that the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [hereinafter: Regulation (EU) 2017/745] – which in itself is binding in Hungary as well without any implementation, it is part of our internal law – contains this term, which is more accurate than the term of the Convention.
According to Section 2(2) of the above Regulation, **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"?
This Article is not included explicitly in Hungarian law (of course apart from the text of Act CCVIII of 2013 of publishing Medicrime Convention in Hungary, which made the Articles of the Convention parts of the Hungarian law), but the EU legislation is satisfactory. The very detailed EU Regulations on medical devices and in vitro medical devices are binding legislative acts without any implementation and they must be applied in their entirety in Hungary as well.

This term is not explicitly included in the relevant EU Regulation, but the text contains these expressions (parts, materials) and their relevant rules in some Articles.

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"?
Neither EU legislator (Member States) nor Hungary consider this very general term of medical devices **document** as a required item in the text of the relevant legislation. EU and Hungarian law also provides detailed rules on the documentation and all the detailed rights and obligations attached to them.

The texts themselves refer to different documentation on several points. For example Section 10(4)-(5) of Regulation (EU) 2017/745 contains detailed rules about the manufacturers' obligations regarding the technical documentation for the devices.

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”?

    According to Section 1 point 11 of the Act XCV of 2005, **manufacture of medicinal products** shall mean the authorized production of medicinal products in a controlled industrial environment.

    The following further conditions are laid down in Section 4 of the Act XCV of 2005:
    Section 4(1) With the exception of magistral formulas produced in pharmacies, medicinal products may only be produced in the territory of Hungary in possession the authorization of the government body for pharmaceuticals granted for this specific purpose. The organization holding a license for the manufacture of a medicinal product shall be construed as the manufacturer of that medicinal product.
    (2) The government body for pharmaceuticals shall authorize the production of a medicinal product if the applicant is able to satisfy the personnel and infrastructure requirements set out in specific other legislation to ensure that the quality of the medicinal products manufactured will be in conformity with the requirements laid down in the marketing authorization. An authorization for the manufacture of a medicinal product shall also constitute entitlement for trading the manufacturer's own products on the wholesale market, on condition that the manufacturer is able to comply in its wholesale distribution operations with the personnel and infrastructure requirements set out in specific other legislation for the wholesale distribution of medicinal products.
    (3) Another precondition for the authorization referred to in Subsection (1) is for the applicant to have liability insurance coverage for any potential claims for damages in connection the technological processes in the manufacture of medicinal products.

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”?
    CC punishes – among others – the **counterfeiting** of medical or medicinal product or the making of counterfeit medical or medicinal product. This distinction exists in the practice as follows:

- counterfeiting of product means the modification of an existing genuine product. A new copy does not come off in this case. The perpetrator makes a product, which differs from the genuine product;
- a counterfeit product gives the appearance of genuine product. In this case a new copy, which is similar to the original product, comes off. The method of the making the counterfeit product or the quality of the result is indifferent. It is not required that the false product seems to be perfect. It has to be only similar to the original product as much as possibility of the deception can be occurred with the using of it.

As an EU Member State, we properly, literally implemented Article 1(1)(c) of the 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 (hereinafter: Directive 2011/62/EU).

Therefore, the term in Section 1 point 42 of the Act XCV of 2005 is literally the same as Article 1(1)(c) of Directive 2011/62/EU: falsified medicinal product shall mean any medicinal product with a false representation – excluding unintentional quality defects – 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 authorization holder,
c) its history, including the records and documents relating to the distribution channels used,
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"?
According to Section 50 of the Act XC of 2017 on the Code of Criminal Procedure (hereinafter: CCP), **aggrieved party** means a natural person or an entity other than a natural person the rights or legitimate interest of whom or which were directly violated or jeopardised by the criminal offence.

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.
Article XV(2) of the Fundamental Law of Hungary states that Hungary shall guarantee the fundamental rights to everyone without discrimination based on any ground such as race, colour, sex, disability, language, religion, political or any other opinion, ethnic or social origin, wealth, birth or any other circumstance whatsoever.

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;
Section 185/A of CC – Counterfeiting of medicinal products
Section 186 of CC – Counterfeiting of medical products

Moreover, CC criminalises the following related acts:
Section 188 – Abuse of poison
Section 189 – Abuse of harmful consumer products
Section 415 – Placing poor-quality products on the market

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;
A National Board Against Counterfeiting (hereinafter: NBAC) was established in Hungary. In NBAC the full spectrum of enforcement and commercial interests are represented including the public administration bodies, public prosecutors, police and customs authorities, trademark and copyright associations, interest groups of commerce and industry, and, not least, the enterprises concerned by counterfeiting. The Government Decree entered into force on 1 February 2008, which was replaced by Government Decree 287/2010. (XII.16.) on National Board Against Counterfeiting still in force. NBAC held its first meeting on 3 March 2008. NBAC created an Action Plan Against Counterfeiting and it has a working group against counterfeiting of medicinal products.

However more sections of this Action Plan fitted to the implementation of Directive 2011/62/EU, some parts of it – for example some point in Field of Action 7 on the repression of counterfeiting of medicinal products and food supplements – are still governing:

- continous review of the relevant law and actions based on the law
- the atteched development of ‘case law’, assisting law enforcement
- fostering the cooperation between the relevant bodies, authorities, in frame of it organisating common trainings, consultations, writing information leaflets
- action against websites, where medicines and medical devices are illegally marketed, and attaching procedural guide and methodology to these actions
- active participation in international authority actions
- active participation in targeted awareness-raising campaigns for consumers shopping online
- awareness-raising of the population about the dangers, threats to public health deriving from falsified medicinal products.

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.
Please see the above answer to Question 3/b.

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**);
Continuous and effective cooperation has been developed between health authority, customs and the police since the implementation of the Medicrime Convention in Hungary. Recently, the cooperation has become more frequent not only between the above authorities, but also between the pharmaceutical wholesalers and pharmaceutical manufacturers concerned. Cooperation is based on the legal mandates, but also includes informal contacts between the relevant authorities.

Furthermore, as was written above, the full spectrum of enforcement and commercial interests are represented in NBAC:

- OGYÉI,
- National Tax and Customs Administration,
- National Food Chain Safety Office,
- Police

are working in cooperation to prevent counterfeiting. The cooperation is continuous and covers the import/export of active substances and end-products, online marketing of medical products, illegal trading of medical products, etc.

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**)
Yes, please see the answer to Question 4/a.

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)**);
   The above-mentioned relevant authorities have designated contact persons between whom the information exchange is continuous and will take the necessary immediate action in a given situation.

   In addition, NBAC has set up a Working Group on Counterfeiting of Medicines, whose members are the authorities involved in the

counterfeiting of medicines, as well as representatives of pharmaceutical wholesalers and pharmaceutical companies who may be affected by the phenomenon.

In 2015, a Cooperation Agreement was issued to record the details of the cooperation jointly with the relevant authorities, NBAC and healthcare providers.

Pursuant to Section 17(1) of the Act XCV of 2005, stakeholders of marketing authorization and pharmacists engaged in the wholesale distribution of medicinal products or in the supply of medicinal products to the public, retail suppliers of medicinal products other than pharmacies, as well as the doctors administering the medicinal products shall report any suspected deficiency in the quality of a medicinal product or production batch, and information on any suspected counterfeit medicinal product to the government body for pharmaceuticals (OGYÉI) without delay upon gaining knowledge about such deficiency. The information may be sent in any way but there is also a dedicated email address for this purpose which is used by health professionals and by the public too.

- 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)**);
  Please see the above answer to Question 4/a. There are no common databases or other special channels to share information yet.

  However, there is a possibility to request data in criminal proceedings. According to Section 261(1) of CCP, in a criminal proceeding, the court, prosecution service, investigating authority or, in cases specified in an Act, the organ conducting a preparatory proceeding may request any organ, legal person, or other organisation without a legal personality to provide data.

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**);
   There is no dedicated department at the police in the fight against drug counterfeiting. Every county police criminal service is involved in this issue. There is a nominee at Directorate General for Criminal Investigation Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) who is responsible for the training of the other police forces and ensures the coordination between territorial police body and the designated unit of Europol.

   The experts of the Ministry of Human Capacities and the Ministry of Justice, and experts of the relevant authorities (OGYÉI, National Police Headquarters, National Tax and Customs Administration) are regularly taking part in training sessions and delegated to international working groups and networks (Working Group of

Enforcement Officers, Expert Group 'Delegated act on safety features for medicinal products for human use', OMCL, etc). NBAC organizes a yearly conference on the topic of the practical use of the anti-counterfeit laws.

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**).
According to Article 22(2) of Medicrime Convention, the designated national contact point which shall be 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 is Adam Panker (panker.adam@ogyei.gov.hu), the colleague of OGYÉI.

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.
We don't have information on that.

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. The relevant rules are in Section 185/A-186 of CC.
Aiding or abetting and attempt of all criminal offences mentioned in CC are criminalized in Hungary in general [Section 10, 12, 14 of CC].

However, it has to be noted that Hungary took the following declaration concerning Article 7: "Hungary reserves the right not to apply Article 7 paragraph (1) of the Convention on the basis of Article 7 paragraph (2) of the Convention."

b. Do the offences in your internal laws require intentional conduct? If no, please provide information.
Yes, they do. CC does not criminalize the negligent behaviour in this regard.

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;

Hungary also criminalizes the preparation of counterfeiting of medicinal products [Section 185/A(7) of CC] or of counterfeiting of medical products [Section 186(4a) of CC].

Furthermore, CC punishes the following similar acts:
Section 188 – Abuse of poison
Section 189 – Abuse of harmful consumer products
Section 415 – Placing poor-quality products on the market

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**).

Section 3 of CC contains the jurisdiction rules. Hungary applies the territorial and personal scope as general jurisdiction rules [Section 3(1) of CC]. CC shall also be applied in any other cases determined in Article 3(2) of CC, consequently Hungary has other jurisdiction principles to apply. It has to be underlined, that the universal jurisdiction principle exists in Hungary [Section 3(2)(ac) of CC].

With regard to the place of criminal acts committed, there is a rule in Hungary, namely the theory of unity of actions. Therefore the criminal offence shall be regarded as committed within the territory of Hungary if any of the important elements (criminal conduct, effect, etc...) realize in the territory of Hungary.

According to Section 3 of CC, the following provisions have to be applied:
Section 3 (1) Hungarian criminal law shall apply to
a) criminal offences committed in Hungary,
b) criminal offences committed on vessels flying the flag of Hungary, or on aircrafts flying the flag of Hungary, being outside the territory of Hungary,
c) acts committed by Hungarian nationals abroad if the act constitutes a criminal offence under Hungarian law.
(2) Hungarian criminal law shall apply to
a) acts committed by persons other than Hungarian nationals abroad if the act

aa) constitutes a criminal offence under Hungarian law and is also punishable under the law of the place where it was committed,
ab) is a criminal offence against the State, except for espionage against allied armed forces and espionage against the institutions of the European Union, whether or not the act is punishable under the law applicable to the locality where it was committed,
ac) is a criminal offence defined in Chapter XIII or XIV, or any other criminal offence to be prosecuted under an international treaty promulgated in an Act,
b) acts committed by persons other than Hungarian nationals abroad against a Hungarian national, or a legal person or other legal entity without legal personality established under Hungarian law, which are punishable under the Hungarian law.
(3) In the cases specified in paragraph (2), the criminal proceedings shall be launched by the Prosecutor General.

Please note, that Hungary implemented the Council Framework Decision 2009/948/JHA on prevention and settlement of conflicts of exercise of jurisdiction in criminal proceedings. Due to this fact, if jurisdiction conflict raises among Member States of the European Union, there is an opportunity for exchanging information or direct consultations. The implemented rules are in Articles 104-107 of the Act CLXXX of 2012 on the judicial cooperation in criminal matters with the Member States of the European Union (hereinafter: Act CLXXX of 2012).

Please note, that Hungary took the following declaration concerning Article 10: "Hungary reserves the right not to apply Article 10 paragraph (1) point d) and paragraph (2) of the Convention on the basis of Article 10 paragraph (4) of the Convention."

Question 8: Corporate liability

Does your system provide that a legal person may be held liable for an offence established in accordance with **Article 11**? Please specify under which conditions.
Yes, it does. The criminal liability of legal persons is indirectly connected to the criminal liability of natural person in Hungary.

Hungary believes that for punishing a legal person, a link must exist between the criminal offence and the legal person. This link would be the benefit and from 1st of July 2013 the commission with the use of the legal person.

Another condition is that the natural person perpetrator, as manager of the legal person, commits the criminal offence, or a member or employee of the legal person commits the criminal offence acting on the business of the legal person, and the criminal offence could have been prevented had the surveillance or control obligations of the manager been properly complied with [Section 2(1) of the Act CIV of 2001 on the criminal measures applicable against legal persons (hereinafter: Act CIV of 2001].

The criminal sanctions can be applied as well if the commission of the criminal offence was known by the manager of the legal person [Section 2(2) of the Act CIV of 2001].

The measures against the legal persons – as a general rule – can only be applied, if the court has determined the criminal liability of a natural person. However, the legislator widens significantly the scope of those cases when a measure can be applied against a legal

person, even if the natural person committing the crime cannot be held criminally liable, though the fact that a crime occurred is obvious [Section 3(2) of the Act CIV of 2001].

The following criminal measures can be taken by the court against the legal persons [Article 3(1) of the Act CIV of 2001]:
a) winding up of the legal person,
b) restriction of the activities of the legal person,
c) fine.

Question 9: Sanctions and measures

a. Please indicate which sanctions internal law provides for the criminal offences established in accordance with the Convention with regard to both natural and legal persons. Please specify whether the sanctions are criminal, civil and/or administrative sanctions (**Article 12, Explanatory Report, paras. 84-91**);
   The following criminal sanctions have to be applied:
   - **in respect of natural person**:
     - preparation of the criminal offence: imprisonment for up to one years;
     - in basic cases: imprisonment for up to three years;
     - in more serious qualified cases: imprisonment for one to five years, or imprisonment for two to eight years;
     - in the most serious qualified cases: imprisonment for five to ten years.
   - **in respect of legal person**: winding up of the legal person, restriction of the activities of the legal person, fine.

   Moreover, it has to be noted, that in respect of a natural person, Section 33 of CC gives a possibility to the judge to impose another punishment with the following conditions: if the maximum of the penalty range for a criminal offence does not exceed three years of imprisonment then confinement, community service, financial penalty, disqualification from a profession, disqualification from driving a vehicle, ban on entering certain areas, ban on visiting sports events, or expulsion may be imposed, individually or in any combination, instead of imprisonment.

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**).
   On the basis of Section 389(b) of CCP, in the course of an investigation, the recognition of a foreign, or a Member State, judgment concerning the suspect, which may be taken into account during the proceeding, shall be ensured.

   Sections 108-111/H of the Act CLXXX of 2012 determines the rules of taking into account the final sentence adjudicated by a Member State of the European Union without any further action.
   Prior conviction has to be taken into account in accordance with Sections 47-48 of the Act XXXVIII of 1996 on the international legal assistance in criminal matters in

relation with third countries (hereinafter: Act XXXVIII of 1996) as soon as the final sentence has been recognized by a competent court.

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**).

Section 80 of CC lays down the rules of the principles of sentencing according to which punishment shall be imposed within the framework laid down in this Act, bearing in mind its objective, ensuring that the punishment is appropriate for the material gravity of the criminal offence, the degree of guilt, the degree of danger the perpetrator poses to society, and other mitigating and aggravating circumstances.

Aggravating circumstances referred to in point a), b), c), d) are parts of the qualified cases of the criminal offences [Section 185/A(3)-(6) of CC, Section 186(2)-(4) of CC].

The commission in a criminal organization *[according to Section 459(1) of CC, a criminal organisation means a group that consists of at least three persons, is established for a longer period of time, is organised hierarchically and operates in a conspiratorial manner to commit intentional criminal offences punishable by at least five years of imprisonment]* has to be taken into account by the court on the basis of Section 91 of CC and in this case the maximum of the penalty range applicable to the criminal offence shall be doubled, but it shall not exceed twenty-five years. Furthermore, CC criminalizes the participation in a criminal organisation by Section 321 of CC.

Aggravating circumstance in point f) has to be also considered by the court on the basis of Section 89 of CC and in this case the maximum of the penalty range of the more recent criminal offence shall be increased by half for imprisonment, but it shall not exceed twenty-five years *[pursuant to Section 459 point (31)(a) of CC, a recidivist shall be considered a special recidivist if he committed the same criminal offence or similar criminal offences both times]*.

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 criminal offences determined by Medicrime Convention are all subject to public prosecution.

   First of all, criminal proceeding has to be launched by ex officio in Hungary. On the basis of Section 4(1) of CCP, the prosecution service or investigating authority shall launch a criminal proceeding ex officio if it becomes aware of a criminal offence subject to public prosecution.

   Secondly, a member of an authority, a public officer, and, if required by law, a statutory professional body shall be obliged to file a crime report regarding a criminal offence subject to public prosecution it becomes aware of in its official competence or in his official capacity, respectively [Section 376(2) of CCP].

The withdrawal of victim's crime report is not possible in Hungary.

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**).
There is no specialized/designated unit in this area, and the related investigations are carried out by the Police Criminal Service.

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**).
Part Six (Section 214-260) of CCP lays down the detailed rules of covert means.

Pursuant to Section 214(4) of CCP, the following covert means may be used in a criminal proceeding:

- **not subject to permission of a judge or a prosecutor** [Section 215 of CCP]
  - using a person cooperating in secret
  - collecting and verifying information relating to a criminal offence
  - use a trap not causing injury or damaging health
  - replacing an aggrieved party or another person to protect his life and physical integrity
  - covertly surveillance of a person, home, other room, fenced area, public area, premises open to public, or vehicle, or an object serving as means of physical evidence, and collecting information on events taking place, and use technical means to record such events
  - disclosing false or misleading information to the person concerned

- **subject to permission of a prosecutor** [Section 2016-230 of CCP]
  - surveillance of payment transactions of
  - offering avoidance of the establishment of criminal liability
  - consented surveillance
  - simulated purchases
  - undercover investigators
  - simulated purchases by members of organs authorised to use covert means and persons cooperating in secret
  - cover deeds, cover institutes, and cover data

- **subject to permission of a judge** [Section 231-242 of CCP]
  - secret surveillance of an information system
  - secret search
  - secret surveillance of a locality
  - secret interception of a consignment
  - interception of communications.

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;
  Section 51(1)(d) of CCP ensures the right of the aggrieved party to inspect case documents produced in relation to a criminal offence that affected him, with the exceptions specified in CCP.

  We would like to indicate in the preface that according to Act CXXXV of 2005 on Crime Victim Support and State Compensation (hereinafter: Victim Support Act) a person is considered a victim if he/she is an injured party of a crime (either felony or misdemeanour) committed in the territory of Hungary. A natural person can also be considered a victim of crime if he/she suffered injury as a direct consequence of a criminal act in particular physical or emotional harm, mental shock or economic loss. The aim of victim support is to mitigate the social, moral and pecuniary injuries of victims whose quality of life has been endangered due to a criminal act. Therefore not only the directly affected person is considered a victim, but also his/her family member, who also has to bear the consequences and takes care of the funeral of a deceased victim. Victim support services are available for victims of every type of crimes, though only victims of violent intentional crimes may be eligible for state compensation.

  The Article 4(1) of the Victim Support Act generally states that the State shall provide services to the victim, after the assessment of his/her needs. Pursuant to Article 4(1)(a), such a service is the providing help for the assertion of interests, in the framework of which – according to Article 4(2) of the Victim Support Act – the victim support service (hereinafter: VSS) shall help victims, in a manner and to the extent they may require, through the legal process of enforcement of their fundamental rights and for having access to healthcare services, health insurance benefits and social welfare services. For this purpose the VSS provides information, legal advice, emotional assistance and other types of assistance.

  The legal provisions on the providing help for the assertion of interests, in addition to the presentation of other services, are also explained in detail in the answers to the Question 12/b. and 12/d.

- assist victims in their physical, psychological and social recovery;
  VSS always provides every victim turning to it for support without eligibility check with all the necessary information about available health and social services. This informational service is always personalized. The victims can also receive basic legal assistance from the bras of VSS and there is also the possibility to receive psychological and emotional assistance. If the VSS receives information on a victim from another authority or public or private body, immediately informs this person (based on his/her known needs) in written form on his/her right to invoke for services and on which type of services he/she could be entitled for.

In addition, pursuant to Article 4(3) of the Victim Support Act, the VSS in the form of instant money aid – as a kind of physical support – covers the victim's extraordinary expenses related to housing, clothing, food and travel, as well as medical and funeral expenses if, as a result of a crime or property violation, the victim is unable to cover such expenses. It is therefore a de facto ambulance so that the basic needs of the victim are not jeopardized.

The Hungarian victim support system rests on three pillars: one pillar is provided by the regional victim support services, the other by the Victim Support Centers, and the third is provided by the free-of-charge victim support line available 24 hours a day, 7 days a week.

In county (capital) government offices operating as regional victim support services, victims may use the services and benefits specified in the Act.

The Victim Support Centers, maintained by the Ministry of Justice, have been opened with the aim of enabling victims to receive the widest possible, more complete and complex support, so that the rights of victims can be enforced at the highest possible level. The tasks of the Victim Support Centers include the emotional assistance provided by a psychologist, the organization and implementation of the actual crisis intervention, the management and follow-up of clients, as well as a wide range of information and prevention activities. The staff of the center can also provide effective help in dealing with the trauma of the crime experienced.

- provide for the right of victims to compensation from the perpetrators.
  The Victim Support Act provides state compensation to victims under certain conditions. According to Article 6(1) of the Victim Support Act needy victims of certain violent and intentional crimes may be eligible for state compensation, if their physical integrity or health has been seriously damaged as a direct consequence of the act. The most important crimes that may be grounds for the compensation claim are murder, assault, THB, kidnapping, rape and robbery, but terrorism is also an applicable crime. Besides the victims of crime, compensation can be provided to a natural person who is a next of kin, adoptive parent, foster parent, adopted child, foster child, spouse or common-law spouse of the deceased or injured victim of a violent intentional crime and who was living with the victim as a domestic partner at the time of the crime. Compensation can also be provided to a natural person whom such a victim is or was obliged to maintain on the basis of a legal regulation, an enforceable court order or official decision or a valid contract. Finally compensation can also be provided to a natural person who arranged for the funeral of such a victim.

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**).

Section 51 of CCP determines the rights and obligations of the aggrieved party. Points (e), (g)-(i) of paragraph (1) ensure the following rights:

- to be informed about his rights and obligations in a criminal proceeding by a court, prosecution service, or investigating authority,
- to make use of the assistance of an aide,
- to enforce a civil claim in a court procedure as a civil party, and give notice of his intent to do so during an investigation,
- to act as a private prosecuting party or a substitute private prosecuting party.

The method of giving information about rights and obligations is ruled by Section 74 of CCP.

According to 375(3) of CCP, the prosecution service or investigating authority shall inform the aggrieved party about instituting an investigation, provided that the identity and contact details of the aggrieved party are known.

The prosecution service shall inform the defendant, his defence counsel, the aggrieved party, the party reporting the crime, and the person who filed a private motion about filing the indictment [Section 423(3) of CCP].

As mentioned above, Hungarian legislation uses a general definition to the notion of the 'victim', however the service granted to the given victim is always personalized, thus the needs of victims with special circumstances are always taken into consideration. Within general victim support, special victim groups are also entitled to specific victim support services. Pursuant to Article 4(1) of the Victim Support Act the State shall provide services to the victim, after the assessment of his/her needs. The following services may be provided to the victim under the law: a) providing help for the assertion of interests, b) immediate financial assistance, c) confirming victim status, d) counselling, e) provision of shelter (safe house). According to Article 4(2) of the Victim Support Act, the VSS, in the framework of providing help for assertion of interests shall help victims, in a manner and to the extent they may require, through the legal process of enforcement of their fundamental rights and for having access to healthcare services, health insurance benefits and social welfare services, provides for this purpose: a) information, b) legal advice, c) emotional assistance, d) other types of assistance, to help victims to get remedy for the injury.

Under Article 24(1) of the Victim Support Act, the VSS shall, inform the victim, after having assessed his/her needs, of: a) the victim's rights and obligations in criminal or misdemeanour proceedings; b) the types of support available to the victim and the conditions governing their application; c) other benefits, allowances and enforcement possibilities provided for by this Act; d) contact details of state, municipal, non-governmental organizations and religious communities involved in victim assistance; e) the possibilities of avoiding repeat victimization, having regard to the type of crime or property misdemeanour.

Pursuant to Article 24(2) of the Victim Support Act if the VSS acquires information on a natural person becoming a victim from a request for assistance submitted to another authority, body or organization, informs the client (according to the

information available regarding the victim's needs) in writing with priority that he/she may be entitled to assistance and if so, that he/she may submit a request claiming the assistance.

Under Article 25(1) of the Victim Support Act, after considering all the circumstances of the case, the VSS shall inform the victim of: a) the health care and health insurance benefits available; b) health services, with or without a referral; c) the address and contact details of the institutions providing the services; d) the rights and obligations of patients; e) the role, name and contact details of the patients' rights representative; f) the content of the health mediation procedure; and other means of enforcement. Under Article 25(2) of the Victim Support Act at the request of the victim, the VSS will assist in: a) accessing health care service as quickly as possible, b) enforcing the right to complain relating to health insurance. Pursuant to Article 25(3) of the Victim Support Act, in order to ensure that the victim has access to the most appropriate health service as quickly as possible, the VSS may enter into a cooperation agreement with the healthcare provider within its area of jurisdiction. Under Article 25(4) of the Victim Support Act the VSS directs the victim, with his/her consents, to a health care provider. The VSS primarily directs the victim to the health care provider with which it has concluded a cooperation agreement.

According to Article 41(2) of the Victim Support Act the VSS compiles a brochure on the most important information for victims and delivers this to the authorities and organs getting in contact with victims. Decree No. 32/2015 IM (Ministry of Justice) (hereinafter: Decree No. 32/2015) on the content requirements of information brochure compiled by the victim support service provides for the minimum information which the brochure must include. Under Article 1(1) of Decree No. 32/2015 the Minister of Justice (as a VSS) draws up an information brochure to ensure that the victims of crime get the necessary information without delay on their rights and on the available services, when getting in touch with an authority for the first time. Under Paragraph (2) of the same Article the brochure can be drawn up generally or for special victim groups according to their age or the criminal act they suffered. It is a very important legal expectation, that the information provided should be phrased in a clear and articulated way, in the simplest available form to be easily understood.

Pursuant to Article 3 of Decree No. 32/2015 the information brochure must at least contain the following information: a) the goal of services available for victims; b) reference to the fact that some services can only be granted under specific circumstances; c) the substance of the individual services; d) reference to the contact information to VSS, including telephone number and e-mail address; e) the contact to the cost-free Victim Support Line; f) information that personalized information can be provided by the victim support services if the victim gets in touch with them. Under Article 4 of Decree No. 32/2015 information on the personalized information that are in accordance with their needs can only be provided by the VSS after the victim gets in touch with them personally via the contacts given on the information brochure.

It shall be highlighted in connection with providing information for the victims under Article 4(3)(a) of Government Decree No. 362/2016 (XI. 29.) on the duties and

competence regarding justice services (hereinafter: Government Decree No. 362/2016) the Ministry of Justice acting as VSS provides personalized information in the victim support proceedings and for this purpose operates continuously without any interruption the cost free Victim Support Line [to which Article 24(4) of the Victim Support Act also refers]. Moreover, victims of crime and property misdemeanour are also provided with the access to the service of 'assertion of interests' in Victim Support Centers maintained by the Ministry of Justice. Under Article 10(4) of Government Decree No. 362/2016 if the information is required through the Victim Support Line by the victim, the information shall be provided by the Ministry of Justice irrespective of whether the victim submitted a request to the capital or regional government administration office, or not.

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)**);

Section 51(1)(a)-(c) and (g) of CCP determine the below rights of the aggrieved party:

- to submit evidence, file motions and observations,
- to deliver a closing address in the course of closing speeches,
- to be present at the trial and other procedural acts specified by an Act, and ask questions as provided for in this Act,
- to make use of the assistance of an aide.

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)**)

Providing help for assertion of interests

According to Article 4(3) of the Victim Support Act VSS shall help victims, in a manner and to the extent they may require, through the legal process of enforcement of their fundamental rights and for having access to healthcare services, health insurance benefits and social welfare services. Moreover VSS provides basic legal advice and assistance to help victims to get remedy for the injury. When psychological or emotional assistance is needed to recover from the trauma caused by the crime, a psychologist is also available within this service. According to Article 36/B(1) of the Victim Support Act the goal of the psychological or emotional assistance is for the victim to regain his/her emotional balance. The emotional assistance includes decreasing the tension caused by the criminal act, to create a secured emotional environment, to channel and voice the occurring tension and frustration or other negative feelings and to help accept the reality and to search for a solution and help the victim to move on. The provided assistance is always based on the individual need of the given victim. In case of a child involved, the VSS should, after considering all the circumstances provide information to the victim on basic child-welfare services, specialist child-protection care and other forms of child-protection, the eligibility of these services, how to apply to them and the contacts to the institutions providing the services.

The legal aid used to be a separate support service, but after 1st November 2015 it is a part of the assertion of interest support service, since it does not include an official decision of the VSS, which only directs the eligible victims to the Legal Aid Service.

Everyone who turns to VSS is entitled to information and advice free of charge. This means, not only victims, but anybody can get advice from VSS. VSS informs the clients on:

- the rights and obligations of victims in criminal proceedings,
- the available forms and the conditions of victim support,
- any other available benefits, allowances and opportunities to assert his/her rights,
- contact details of state, local government, civil and ecclesiastic organizations involved in supporting victims of crime, and
- how to avoid repeated victimization. [Article 24(1) of the Victim Support Act]

The Ministry of Justice also runs a nationwide 24/7 telephone service, free of charge (Victim Line 06 80 225 225), where victims can get personalised information.

Instant monetary aid

According to Article 27(1) of the Victim Support Act instant monetary aid is to cover the victim's extraordinary expenses arising as a consequence of the crime suffered, in order to provide all basic needs of the victim. It is not a compensation for the damages, rather a crisis aid for expenses concerning housing, clothing, nutrition, travelling, medical and funeral costs, respectively.

Maximum amount of the aid increases every year depending on the average gross monthly income in the country. Instant monetary aid (such as state compensation) is financed from the national budget [its amount is maximized (HUF 141,875 in 2020)]. The chapter within the national budget for victim support is not limited. That means, in case it runs out mid-term, it can (and must) be filled up by the Ministry of Justice.

Since 1st November 2015 the VSS has the possibility to give vouchers for different services (for example for traveling, food or funeral), rather than money.

Certification of victim status

If, for any reason a victim need a certificate to prove that he/she has been a victim the VSS issues this certificate on the victim's application, according to Article 4(4) of the Victim Support Act. Also in case a lawyer is needed (for example to submit a petition to the court), VSS issues a certificate on the victims status and refers the victim to the Legal Aid Service. Victims of crime are entitled to legal aid on more favourable terms than regular clients. There is no deadline, but there is an application form for this kind of support. Free legal aid can only be provided to needy victims.

Shelter (safe houses)

Victims of THB are entitled to get free accommodation, nutrition, clothing and mental health care in a shelter for 90 days. During this period, the victim is given assistance for his social reintegration. Should 90 days prove to be insufficient, the victim may stay for additional 90 days.

State compensation

According to Victim Support Act needy victims of certain violent and intentional crimes may be eligible for state compensation, if their physical integrity or health has been seriously damaged as a direct consequence of the act. The most important crimes that may be grounds for the compensation claim are murder, assault, THB, kidnapping, rape and robbery, but terrorism is also an applicable crime.

Besides the victims of crime, compensation can be provided to a natural person who is a next of kin, adoptive parent, foster parent, adopted child, foster child, spouse or common-law spouse of the deceased or injured victim of a violent intentional crime and who was living with the victim as a domestic partner at the time of the crime. Compensation can also be provided to a natural person whom such a victim is or was obliged to maintain on the basis of a legal regulation, an enforceable court order or official decision or a valid contract. Finally compensation can also be provided to a natural person who arranged for the funeral of such a victim. The maximum amount of state compensation in 2020 is HUF 2,128,125.

Victims have to be needy to be entitled to compensation. Indigence is defined by the income position of the applicant.

The form of state compensation can be:

- lump-sum cash payment if it aims the compensation of economic loss caused by the crime, or
- regular monthly instalments if it aims the compensation of the diminution of regular income.

State compensation has a special procedural system. The procedure consists of two phases: assistance and decision-making. The system is in accordance with the EU directive requiring Member States of the EU to establish an assisting and a deciding authority to deal with compensation cases.

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)**);

Chapter XIV of CCP lays down the detailed rules of special treatment in criminal proceedings.

In the framework of special treatment (Section 85-86 of CCP), the court, prosecution service or investigating authority shall ensure

- that the person concerned may exercise his rights and perform his obligations despite all obstacles that may arise from the circumstances serving as grounds for his special treatment,
- the proceeding with special care during communication,
- the proceeding with special care to protect the privacy of the person concerned in the course of conducting the criminal proceeding,
- to provide enhanced protection for personal data of the person concerned that serve as grounds for his special treatment, in particular data concerning his health,
- to facilitate the use of an aide by the person concerned,

- taking into account the personal needs of the person concerned in the course of planning and performing procedural acts, and carrying out procedural acts requiring the presence of the person concerned without delay,
- preparing each procedural act requiring the presence of the person concerned in a manner that allows for it to be carried out without any repetition,
- that the person concerned does not meet unnecessarily any other person participating in the criminal proceeding in the course, or at the location, of a procedural act, especially if special treatment is justified by his relationship to that person,
- to carry out the procedural act in a room used, or made suitable, for such acts if the exercise of the rights and the performance of the obligations of the person concerned may not be facilitated, and the person concerned may not be spared by any other means or measures,
- to make image and sound recordings at procedural acts requiring the participation of the person concerned,
- to secure the presence of the person concerned at a procedural act by means of telecommunication,
- the authorities may exclude the public from a trial or a specified part of a trial,
- the authorities may take any other measures determined by CCP,
- the authorities may provide protection and
    - order all identifying personal features of the person concerned to be distorted by technical means when using any means of telecommunication,
    - order the production of a copy of an image and sound recording of a procedural act where all identifying personal features of the person concerned are distorted by technical means,
    - restrict, pursuant to this Act, the right of a defendant or defence counsel to be present at a procedural act,
    - restrict the right to ask questions of a person who is present at a procedural act involving the person concerned, by permitting that motions for questions be submitted,
    - refrain from any confrontation involving a witness requiring special treatment,
    - order, ex officio, the personal data of the person concerned to be processed in a confidential manner,
    - initiate ordering personal protection for the person concerned,
    - declare the person concerned to be a specially protected witness, or initiate such a declaration,
    - initiate the conclusion of an agreement for including the person concerned in a Protection Programme.

Furthermore, Section 90-93 of CCP lays down the detailed rules of the specially protected witnesses. If the court declares a specially protected witness – among others – the case documents shall be handled in a confidential manner, only certain persons determined by CCP may be present at a procedural act, procedural acts requiring the participation of a specially protected witness may be carried out primarily through a requested court or delegate judge, and a defendant or defence

counsel may not be present at such acts, and the presence of a specially protected witness at a procedural act may be allowed by way of means of telecommunication.

Section 99 of CCP regulates the processing personal data in a confidential manner, and Section 181 of CCP ensures the possibility to provide written testimony.

According to the Act on Witness Protection (Act LXXXV of 2001) a Protection Programme is based on an agreement between the protected person and the Witness Protection Unit. The Unit shall determine the methods of protection in the agreement, taking into account the extent of the threat and the opinion of the authority entitled to initiate protection. As a protective measure the authority responsible for the protection may

- relocate the person concerned from his or her permanent or temporary residence to a safe place or transfer a prisoner who has entered the Program to another state penitentiary institution;
- application of physical (personal) protection;
- order data closure in various registers;
- oblige data processing authorities to report any inquiry concerning the person involved;
- change the name;
- change of full identity;
- relocate the person concerned abroad in the framework of international cooperation.

The Witness Protection Program further includes psychological, social, financial, humanitarian and legal assistance to the person concerned.

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**).

Under Section 75(1) of CCP, legal aid may be granted to a defendant or a natural person aggrieved party, party with a pecuniary interest, or other interested party to facilitate the exercise of his rights, provided that he is unable to cover criminal costs, in whole or in part, due to his income and financial situation. However, legal aid shall be granted to a defendant, aggrieved party, party with a pecuniary interest, or other interested party regardless of his income or financial situation if the law specifies that [Section 75(3) of CCP].

Pursuant to 76(b) of CCP, legal aid shall cover advancing by the State the fee and costs of a patron lawyer, as well as bearing such fee and costs in situations specified in the Act on legal aid, when granted to an aggrieved party, a party with a pecuniary interest, or another interested party.

According to Article 20(3) of the Medicrime Convention, each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.

1. In order to meet this requirement Article 3(1)(g) of the Act LXXX of 2003 on Legal Aid (hereinafter: Legal Aid Act) states that the extrajudicial aid, providing legal services (legal advice, preparing submissions or other papers, and inspect the

documents of the case by the legal aid provider) may be granted to a party if the party is a victim of a crime and is in need of legal advice or requires assistance for the preparation of a petition (statement of claim, request, complaint, indictment etc.) in order to file charges, understand their procedural rights and obligations, or institute a lawsuit for compensation for the damage caused by the crime or for any injury, legal or otherwise. Legal aid can be granted through the organizational units of the county government offices performing legal aid tasks (hereinafter: legal aid services).

Taking into account the interests of fairness, Article 1(2) of the Legal Aid Act states that the State shall pay or advance the legal aid providers in lieu of the Parties for the pertinent costs and fees in the amounts specified by law. If, owing to their income and financial situation, a party becomes entitled to have the State assume payment of the legal services fee, the party shall have recourse to legal services without cost. If the State assumes advance payment of the legal services fee, the party shall repay the State the advanced fee within the period stipulated in the resolution authorizing the aid.

2. Pursuant to Article 17 of Legal Aid Act the state also provides support in the framework of legal aid in ongoing criminal proceedings. Accordingly the State shall, in cases specified by law, bear or advance the fees and expenses of the probationary lawyer to the victim, the private prosecutor, the substitute private prosecutor, the private party, the property stakeholder and other interested parties. The substance of the support specified in Paragraph (1) shall be determined by CCP.

In the case of a criminal offense, the legal service fee will be paid by the state instead of the client, if its monthly net income does not exceed 86% of the gross monthly average earnings of the second year before the current year, published by the Central Statistical Office (in 2020 is 283 750 Forints).

3. Detailed rules on relevant eligibility conditions are set out in the Annex to this note.

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**).

We have two scenarios in this regard:

1. If a Hungarian victim suffered any injury due to a counterfeit medicine in the territory of an EU Member State, he can make a complaint at the Hungarian authority which will forward it to the Member State judicial authority competent for the place of commission in accordance with Section 107/A of the Act CLXXX of 2012.

2. When a victim from an EU Member State suffered any injury in Hungary because of a counterfeit medicine, the Hungarian authority receives the complaint in accordance with Section 107/B of the Act CLXXX of 2012.
In relation with third countries, Section 45 of the Act XXXVIII of 1996 ensures the possibility to file the complaint at a foreign State.

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;
According to Section 51(1)(g) of CCP, one of the aggrieved party's rights is to make use of the assistance of an aide. Chapter XI of CCP lays down the detailed rules of aide.

The State shall, within the framework of providing legal aid, provide assisted persons with the right to have recourse to legal aid. Legal aid providers shall provide extrajudicial legal services and/or act as advocates under the Legal Aid Act. According to Article 66(1) of Legal Aid Act associations, foundations, and nationality self-governments engaged in activities related to the provision of legal protection, universities offering legal education (hereinafter referred to jointly as 'organizations providing legal aid') and attorneys, law firms and European Community lawyers permanently working in Hungary (hereinafter referred to jointly as 'attorneys') could become legal aid providers.

According to Article 68(1) of the Legal Aid Act attorneys who have been entered in the register as legal aid providers as well as lawyers acting on behalf of organizations providing legal aid may only perform the legal services that, by virtue of legislation relating to their activities, fall within the scope of their competence. According to Article 68(2) of the Legal Aid Act a legal aid provider organization entered in the register may only act as an advocate for an injured party, private prosecutor, substitute private prosecutor and private party in criminal proceedings if it satisfies the conditions set out in Article 61(3)(e) of CCP; it may not act as an advocate for other persons in 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**)
These requirements are fully granted by legislative and other measures. OGYÉI – as the responsible authority for the supervision of manufacturing and wholesale trade of medicinal products – makes certain through their colleagues working as GMP and GDP inspectors that manufacturing of medicinal products meets the requirements stated in the Marketing Authorisation and is proceeded according to GMP directives, and wholesale trade of medicinal products meets the requirements stated in the concerning laws.

According to Section 4(6a) of the Act XCV of 2005, if based on the findings of an inspection of any manufacturing site of medicinal products, or of active substances and excipients used as starting materials for the manufacture of medicinal products,

or the facilities of wholesalers of medicinal products, carried out by way of sampling and analysis or the inspection of the related documents it is determined that the inspected entity does not comply with the legal requirements and/or the principles and guidelines of good manufacturing practice or good distribution practices as provided for by Union law, the government body for pharmaceuticals shall take the measures necessary and shall send its findings to the European Medicines Agency.

b. Which legislative or other measures have been taken to ensure the safe distribution of medical products? (**Article 18 para. 2**)
Please see the answer to Question 13/a.

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?
     No training was held as described.
   - the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?
     The police did not take any action as described.

     The most effective and best-known approach in fighting against counterfeit drugs is to ensure a closed chain of the distributional system. In Hungary, the domestic legal medicine-market is strictly controlled. OGYÉI controls the route of the medicine all the way till the pharmacy, meaning the quality of the drugs, their efficacy and safe usage, also the activity of the medicine wholesalers. The National Public Health and Medical Officer Service then checks on the retail-merchandising of the medicines (pharmacies, small retail shops with particular authorisations). Controlling this latter activity OGYÉI also participates in validating the electronic information systems that supports the drug retail outside the pharmacies.

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**);
Following the actions announced by Europol and Interpol, the relevant authorities will be briefed by the police in a joint press conference, during which the results will be presented and the dangers will be presented in order to prevent similar incidents.

Police currently have no plans to launch another campaign.

NBAC organizes annually awareness-raising campaigns for the general public in which OGYÉI regularly takes part. These campaigns usually operate with films, workshops, competitions for youngsters, and similar activities.

Beyond the above, OGYÉI, the National Tax and Customs Administration of Hungary, the National Food Chain Safety Office, and the Hungarian Police are regularly taking part in international joint actions like MISMED, VIRIBUS, PANGEA, etc.