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MEDICRIME COMMITTEE

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211)

Questionnaire for the 1st thematic monitoring round:

The protection of public health through the MEDICRIME Convention in times of pandemics

As adopted by the MEDICRIME Committee on 27 May 2021

Replies should be addressed to the MEDICRIME Committee Secretariat

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by 30 November 2021

Introduction

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force on 28 October 2011, requires the criminalisation of offences set out in the Convention in Articles 5-8. It sets out that states, in Europe and beyond, shall adopt specific legislation to prevent and combat threats to public health by criminalising certain acts, protecting the rights of victims of the offences established under the Convention, and promoting national and international co-operation.

2. The Committee of the Parties to the Convention (also known as the "MEDICRIME Committee"), established to monitor whether Parties effectively implement the Convention (Rule 25 of the Committee's Rules of Procedure), decided that:

> *"3. The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee."*

3. As available data show that offences involving medical products committed during a pandemic target critical funding through fraudulent scams, counterfeiting of vital protective personal equipment and critical medical devices to save lives and to detect the presence of the disease, and attacks on critical infrastructure in the fight against the disease, the MEDICRIME Committee decided that the first monitoring round would focus on "The protection of public health through the MEDICRIME Convention in times of pandemics".[1]

4. On 27 May 2021, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to offences involving medical products and similar crimes involving threats to public health and related to a pandemic. The replies to the questionnaire will be assessed against the related background information provided by the Parties when answering the "General Overview" questionnaire on the implementation of the MEDICRIME Convention (hereinafter "Country Profile Questionnaire" or "CPQ") and any other relevant information from reliable sources.

5. It is recalled that, 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 co-ordinate 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 questionnaires 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.*

[1] Committee of the Parties of the MEDICRIME Convention, *List of decisions*, 3rd Plenary meeting (1-3 December 2020), T-MEDICRIME-(2020) LD, paragraph 4.5.

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."

PRELIMINARY REMARKS

6. As in the country profile questionnaire, the provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without automatically 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.

7. This thematic questionnaire does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. It focuses only on specific legislative and other measures taken or envisaged to protect public health from counterfeiting of medical products and similar crimes in the context of pandemics.

8. Responses to this thematic questionnaire will be understood against the background information submitted by Parties in reply to the CPQ. Whenever warranted, Parties are invited to refer to such information. Where questions overlap between the CPQ and this questionnaire, the replies to the latter will be assessed by the Committee in order to prepare its implementation reports of the Convention with respect to the monitoring theme.

9. For the purpose of this questionnaire, the notion of pandemic will include the COVID-19 pandemic as well as other major health crises declared by the World Health Organisation as pandemics, epidemics or public health emergencies of international concern (PHEIC), including the Zika virus epidemic in 2015, the Ebola pandemic in 2014, the Middle East Respiratory Syndrome (MERS) in 2012, the H1N1 Influenza pandemic in 2009, the H5N1 outbreak in 2005, and the severe acute respiratory syndrome (SARS) in 2003.

10. If there are differences with the information provided in the responses to the CPQ, Parties are kindly requested to specify which State bodies/agencies and, where relevant, NGOs, contributed to responding to this questionnaire.

11. As with the CPQ, Parties are kindly requested to:

    a. answer the questions regarding 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;
    b. provide the relevant text (or a summary thereof), in English or French only, whenever questions/answers refer to legislation or other regulations;

c. respond to all questions marked **mandatory** as they are essential to the monitoring round. It would be appreciated, where possible, if all questions marked **optional** could also be answered.

Prevention and Training

This section aims to collect information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics. The questions concern all those whose responsibilities it is to procure and supply medical products, and those who encounter them or their impact on public health. This section concerns awareness-raising programmes aimed at these people in particular, as well as the public in general. It concerns prevention measures aimed at raising awareness of the availability of counterfeit medical products.

Question 1. **(mandatory)**

Which legislative, policy, strategic and other measures have been taken to provide training with a view to preventing counterfeit medical products, active substances, excipients, accessories, parts and materials to:

a. those involved in both public and private procurement programmes, wholesalers, and distributors of medical products to ensure that they are competent to prevent and detect counterfeit medical products and conducts that contribute to the commission of similar crimes involving threats to public health, having regard to the impact of a pandemic (Article 18.1, 2 and 3. a and c)?

These above requirements are fully granted by legislative and other measures. The National Institute of Pharmacy and Nutrition (OGYÉI) – as the responsible authority for the supervision of manufacturing and wholesale trade of medicinal products – examines through their colleagues working as Good Manufacturing Practice (GMP) and Good Distributing Practice (GDP) inspectors whether manufacturing of medicinal products meets the requirements determined by the Marketing Authorisation and is proceeded according to GMP directives. Wholesale trade of medicinal products meets the requirements stated in the concerning laws.

However, no specific training was held in this regard.

b. healthcare practitioners, police, customs, and health product regulators?

No dedicated training was held for the police. National Board Against Counterfeiting (hereinafter: NBAC) was established in Hungary. The full spectrum of enforcement and commercial interests are represented in NBAC, including the public administration bodies, public prosecutors, police, National Tax and Customs Administration, trademark and copyright associations, interest groups of commerce and industry, and, not least, the enterprises concerned by counterfeiting. The Government Decree on which the NBAC was set up entered into force on the 1st of February 2008. NBAC still works under the Government Decree 287/2010. (XII.16.). NBAC created an Action Plan Against Counterfeiting and it has a working group against counterfeiting of medicinal products. This Action Plan fosters the cooperation between the relevant bodies, authorities, in frame of it organising common trainings, consultations, writing information leaflets.

Information booklets were made for customs about vaccines and medical devices. The purpose of these booklets was to help customs officers to recognize falsified vaccines and medical products. Although the supply chain of vaccines is centralised in EU countries and there are no private arrangements for the supply of the vaccine to corporations, companies, or individuals, the trade of falsified vaccines cannot be completely ruled out. Therefore customs needed sufficiently detailed information about vaccines. These booklets were made by OGYÉI, pharma-wholesalers and NBAC.

c. specialised investigation units/bodies in the investigation of counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?

No special training was held for the police. There is no dedicated department at the police for the fight against counterfeiting medicines. 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) (Ibolya Csako lt. colonel) 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. In general, conducting of financial investigations are mandatory for all criminal offences.

Question 2. (optional)

Are there any oversight programmes to assess the frequency and effectiveness of the training provided? If so, are there revision programmes to ensure remedial actions of any deficiencies (Article 18.1, 2 and 3. a)?

No, there is no national programme in this regard.

Question 3. (mandatory)

Are there awareness-raising and training programmes for all of those mentioned in question 1.a and b above and for persons and entities responsible for cleaning and waste disposal on the disposal of medical product waste at all stages of the process to prevent the recycling of medical products for the further manufacture of counterfeit medical products and instrumentalities used in the counterfeiting of medical products?

There is no awareness-raising and training programme for health workers and police.

However, in general, the NBAC has set up a Working Group on Counterfeiting of Medicines, members of which are the authorities involved in the counterfeiting of medicines, as well as representatives of pharmaceutical wholesalers and pharmaceutical companies which may be affected by the subject.

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

The Act XCV of 2005 on Medicinal Products for Human Use and Amendments to Other Laws Regulating the Pharmaceutical Market (hereinafter: Act XCV of 2005) stipulates to which stakeholders and authorities quality defects and deficiencies have to be reported. Pharmacists involved in the wholesale distribution of medicinal products or the supply of medicinal products to the general public, retail suppliers of medicinal products other than pharmacies and doctors who administer medicinal products shall report suspected defects in the quality of medicinal products or batches of medicinal products without delay and inform OGYÉI immediately of any suspected falsification or deficiencies of medicinal products.

Question 4. (optional)

Please outline any reviews on the effectiveness of the governance and supervision of medical product waste disposal. Are there any awareness-raising programmes on the importance of proper disposal and the risks that can arise from inadequate governance and supervision?

There is no programme for health workers and police.

Question 5. (optional)

Apart from the above-mentioned general measures, please briefly describe the details of specific preventive actions targeted at specific medical products involved in any recent pandemic as well as the results achieved.

During Covid-19 pandemic, both police and Operational Group for Protection against the Coronavirus Pandemic (this is a governmental body) regularly informed the public about the dangers of fake vaccines and fake PCR tests.

Education

This section aims at identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products.

Question 6. (mandatory)

Please elaborate on the strategies, policies and other measures that have been planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, in particular those that may be encountered during a pandemic (Article 18.3.b):

a. on purchasing conducts of medical products, including through real world/physical and virtual means, such as online and e-commerce platforms and social media;

During Covid-19 epidemic, both police and the Operational Group for Protection against the Coronavirus Epidemic regularly informed the public about the dangers of fake vaccines and fake PCR tests. Public was also informed that the Government would provide vaccination to everyone free of charge. All vaccine manufacturers are only affiliated with the Government, individual sales of the vaccine are not possible.

b. on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems;

The Police and the National Tax and Customs Administration are involved in actions announced by Europol and Interpol. They inform the public about the results of these actions, drawing attention to the dangers of products obtained on the Internet or from other illegal sources.

Action Plan Against Counterfeiting which has launched by NBAC take

- action against websites, where medicines and medical devices are illegally marketed, and attaching procedural guide and methodology to these actions,
- active participation in international actions by authorities,
- active participation in targeted awareness-raising campaigns for consumers shopping online,
- awareness-raising of the population about dangers, threats to public health deriving from falsified medicinal products.

c. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.

Several awareness-raising information are published in the news by the authorities.
http://www.police.hu/hu/hirek-es-informaciok/legfrissebb-hireink/zsaru-magazin/kutatjak-az-alvakcinat
https://koronavirus.gov.hu/cikkek/orfk-senki-ne-doljon-be-az-internetes-bunozok-vakcinahirdeteseinek

Are there any reports on the results of these measures? If so, please attach them to your responses to this questionnaire.

Since the beginning of this current pandemic, the public is continuously informed and educated about counterfeit medical products (like face masks, medicines, and sanitizers), rational consumption of medical products, vaccination, and similar topics. Due to the unexpected pandemic situation, the education of the civil society was not pre-planned but it was coordinated by the Epidemiological Operative Coordinating Body.

Question 7. **(optional)**

Do public authorities have a policy to encourage or support the involvement of civil society (such as industries, publishers, academia, etc.) in the promotion of measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context? If so, please provide details.

NBAC was established in Hungary in which 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. NBAC held its first meeting on 3 March 2008 and was active through the pandemic too.

Question 8. **(optional)**

Is civil society actively engaged in raising public awareness of the risks arising from counterfeit medical products (Article 18. 3, b)? If so, please provide details.

Please see the previous answer with regard to question 7.

Question 9. **(mandatory)**

Which legislative provisions, strategies, plans and preventive measures have been taken to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8. a, and 18. 3. b)?

As we stated above (Question 6.) during the Covid-19 epidemic, both police and the Operational Group for Protection against the Coronavirus Epidemic regularly informed the public about the dangers of fake vaccines and fake COVID-tests. The public was also informed that the Government would provide vaccination to everyone free of charge and individual sales of the vaccine are not possible. The medicinal product offers – especially vaccines and COVID-test offers – were continuously monitored by health authorities and if necessary proceedings have been initiated. (A private vaccination center offered a pre-booking option of vaccines from unknown sources but after a consumer protection procedure the promotion was withdrawn and the money was paid back.)
During the pandemic, the Operational Group for Protection against the Coronavirus Epidemic controlled the strategies and the prevention of any unlawful dissemination of information. Since the general public was continuously informed within the above-mentioned awareness-raising campaign there are no other parallel campaigns are required currently.

Victims

This section aims at identifying measures focused on the protection of victims' rights.

Question 10. **(mandatory)**

Is there any national law and policy for the protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic due to the increased risks arising? If yes, please specify it. If not, what steps are being planned, if any, for the setting of such policy or in the absence of which, for victims of crime relating to counterfeit medical products generally (Article 19)?

Under Section 1 of Act CXXXV of 2005 on Crime Victim Support and State Compensation (hereinafter referred to as '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 (as a general rule). 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 harms, 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.

The relevant Hungarian legislation uses a general definition of the victim, however the service is personalized in every case, so that the needs of women and girls as victims are also taken into consideration. Victim Support Act provides victim assistance to all victims of crime and property infringements, i.e. it does not differentiate between victim groups. At the same time, victim support is offered and provided in each case tailored to the individual needs of the victims.

In Hungary the Victim Support Service (hereinafter referred to as 'VSS') supports all victims of any kind of crime in general. (Thus it is considered as a generic victim support, in Hungary we only have a couple of specific support services, for example for victims of human trafficking and victims of domestic violence).

Question 11. **(optional)**

Are measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4)?

Yes, the general rules have to be applied to the pandemic time as well. Section 51 of the Act XC of 2017 on the Code of Criminal Procedure (hereinafter: CCP) establishes the rules of rights and obligations of aggrieved parties during the whole criminal proceedings. The method of giving information about rights and obligations is ruled by Section 74 of CCP. In addition, Chapter XIV of CCP contains special rules for persons in need of special treatment. Please see the relevant text.

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.

Victims have the right to participate and make statements in criminal proceedings. Legal assistance is available for them from the very beginning of the criminal proceedings. The victim support services are oriented by the

specific needs of victims (to explore these, the authorities concerned must make individual assessment for victims). Thus, there are no specific provisions for victims of crime relating to counterfeit medical products, because the age and other circumstances of the specific victim has to be taken into consideration in all cases and the offered services are in accordance with this individual assessment.

The 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 staff members 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.

Victim support includes the services and the institution of state compensation. The following services may be provided to the victim: a) providing help for the assertion of interests, b) immediate financial assistance, c) confirming victim status, d) counseling, e) provision of shelter (safe house). Services are basically immediate forms of assistance that provided unconditionally to the victims. Victims are entitled to these services free of charge without eligibility check.

VSS shall assist 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. The list is not exhaustive in order to ensure the enforcement of the special needs the individual victims may have. In this context, emotional support is worth highlighting. When psychological or emotional assistance is needed to recover from the trauma caused by the crime, a psychologist is also available within this service. 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. Emotional support (help from a psychologist) can be a short-term assistance but basically it is a long-term help (therapy-based treatments consisting of a series of meetings). 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.

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 personalized information.

The provisions of Act LXXX of 2003 on legal aid (hereinafter referred to as 'Legal Aid Act') provide the possibility for victims of crimes for legal aid with a reduced rate. As a general rule only a party in need is entitled to legal aid services, other victims may only be entitled to a reduced rate.

The access to the proceedings is primarily provided for the victims by the institution of legal aid. Though under the Victim Support Act victims shall be provided with legal assistance by the VSS but this assistance is merely a

basic counseling of a general nature. If the victim needs legal advice or drafting legal instruments in connection with the specific case, the VSS issues a certificate confirming his/her status, based on which Legal Aid Service provides the victim with access of the legal aid services with a reduced cost.

Aid may be granted for extrajudicial proceedings, in civil actions and administrative proceedings, and in criminal proceedings. (These aids may only be granted if the other conditions laid down in the Legal Aid Act are met.)

Legal aid providers shall give the parties legal advice or prepare submissions or other papers for them, and - if so authorized - inspect the documents of their case, and 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.

Within the framework of legal aid, the State shall provide representation to the plaintiff, defendant, intervenor (third party), interested party, petitioner and respondent through an advocate in contentious and – with the exception of enforcement procedures – non-contentious civil proceedings, administrative actions, other administrative court proceedings and non-contentious administrative proceedings as provided for by law, and shall advance or bear the costs thereof on behalf of the party.

In criminal proceedings, the State shall, within the framework of providing legal aid, provide the following support under the conditions set out in the Legal Aid Act:
a) advancing the advocate's fee and expenses on behalf of the injured party, private prosecutor, substitute private prosecutor, private party, stakeholder and other interested party, and bearing such fees and expenses in cases provided for by law;
b) advancing and bearing the fee and expenses of the mandated lawyer on behalf of the defendant.

The content of the support is regulated in CCP.

Question 12. (optional)

What measures are provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceeding and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health? Please provide information on any such organisations and groups/bodies. Please provide information on any assessment of the effectiveness of such involvement by such providers (Article 20.5).

The general rules have to be applied to the pandemic time as well. According to Section 59-60 of CCP, to represent and protect the rights and legitimate interests, and facilitating the exercise and performance of the rights and obligations of – among others – aggrieved parties, certain people determined by CCP may participate in a criminal proceeding as an aide. Please see the relevant text.

The regional victim support services, the Victim Support Centers and the Victim Support Line provide information and assistance tailored to the individual needs to victims of all crimes.

VSS cooperate and maintain contact with both state bodies, non-governmental organizations and religious communities. As a result of this cooperation, in case a victim support service is unable to provide direct assistance through its services or that a victim needs a kind of service that can better be provided by another organization, the service directs the victim concerned to governmental or non-governmental organizations as well as to church best suitable to providing personalized, fast and efficient assistance.

For this reason, the Ministry of Justice have concluded numerous cooperation agreements with organisations listed above.

We are not aware of any non-governmental organisations that would deal with victim support in those crimes that fall into the scope of Medicrime.

Question 13. (optional)

Is civil society actively engaged in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b)? If so, please provide details.

We are not aware of this.

Question 14. (optional)

What measures are in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention? Is there any oversight to assess the effectiveness of such measures? If so, please briefly describe the results (Article 22.1).

The Victim Support Line (06 80 225 225), which is available free of charge 24 hours a day, is run by the Ministry of Justice to ensure that citizens who are victims can obtain information outside office hours. By calling the Victim Support Line, victims can obtain legal information and advice on their rights and obligations in criminal proceedings, the types of assistance available, the conditions and procedures for applying for assistance, and the best way to solve the problem they are facing.

Cooperation and information exchange

This section focuses on the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation.

Question 15. (mandatory)

Please provide information on measures that your country has taken or plans to take to adopt a national strategy and/or formal action plan on cooperation and information exchange between authorities/bodies to combat counterfeiting of medical products and similar crimes and whether they specifically make provision for pandemic situations (Article 17.1).

There is no national strategy. Not especially in the context of pandemics but even before that, continuous and effective cooperation has been developed between health authority, National Tax and Customs Administration 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.

Police has set up an online anti-drugs and anti-counterfeiting task force with representatives of the relevant authorities. This working group will develop recommendations and methodological guidelines in this area.

Question 16. (optional)

a. Is the implementation of such national strategy and/or action plan supported and underpinned by enabling legislation for the transfer and receipt of information and data

between authorities/bodies and to and from other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2)?

b. Are there specific Memorandum of Understanding (MOU) and/or Data Sharing Agreements (DSA) between bodies, at national and international levels, to give effect to arrangements between authorities/bodies in combating counterfeit medical products and similar crimes. Have they been adopted specifically because of the COVID-19 pandemic?

There is a co-operation agreement between the police and the National Tax and Customs Administration, but it is not limited to the fight against counterfeiting of medicines. It generally applies to all criminal offenses.

There is a Data Sharing Agreement between the National Tax and Customs Administration (NAV) and the National Institute of Pharmacy and Nutrition (OGYÉI) for better control of the import and export of active substances. It was adopted because the VAT exemption for the importation of goods into the EU not exceeding EUR 22 has been removed from the beginning of July 2021 and not specifically because of the COVID-19 pandemic. As all goods imported into the EU are subject to VAT more small packages containing active substances will come into the sight of the customs.

c. Please describe briefly, and without going into detail, the practical measures that ensure the implementation and effectiveness of the MOUs and DSAs, including periodic reviews.

Question 17. (optional)

Please state on cooperation arrangements which authority has the lead and which participate in the operation of the plans and what oversight exists on the operation of the plans. Please describe briefly, without going into detail, the main areas of responsibility of the participating authorities.

Please see the previous answer with regard to question 16.

Question 18. (optional)

Do any arrangements involve cooperation arrangements with civil society, with industry or service providers (such as financial and money transfer services, e-commerce, social media platforms providers, logistics – including postal and delivery services, etc.)? If so, please briefly describe these arrangements and whether they took place during or as a result of a pandemic.

Police does not have cooperation agreement with the mentioned stakeholders.

Question 19. (optional)

Please provide details on the membership or arrangements with bodies/groups dedicated to combating counterfeit medical products and similar crimes, whether investigative or advisory in nature. In your reply, please differentiate bodies/groups that put an emphasis on counterfeit medical products but are not solely dedicated to combating counterfeit medical products and similar crimes involving threats to public health.

Continuous and effective cooperation has been developed between health authority, National Tax and Customs Administration 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.

There is a MoU between Police and Hungarian AntiDoping Group from 2016, and the cooperation is very effective.

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

- The National Institute of Pharmacy and Nutrition,
- National Tax and Customs Administration,
- National Food Chain Safety Office,
- police

cooperate 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.

Question 20. (optional)

Does the national strategy/action plan on counterfeit medical products stipulate or facilitate the establishment of a point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities? Is there any oversight of the effectiveness of this process? Please provide information on the effectiveness of this process.

There is no national strategy but OGYÉI is participating in the Single Points of Contact (SPOC) Network of EDQM, WHO, and HMA-WGEO (Working Group of Enforcement Officers) with delegated colleagues. In Hungary both the Police and OGYÉI are members of WGEO.

Question 21. (optional)

Is there a point of contact specified for the international exchange of information relating to the counterfeiting of medical product, such as product alerts and analytical reports from laboratory investigations, that has different arrangements from other points of contact? Please provide any rationale for this difference.

Yes, a colleague of OGYÉI and Police are a point of contact.

Question 22. (mandatory)

Is the exchange of information or transfer and receipt of data and evidence between bodies/countries supported and underpinned by enabling legislation?

The general rules have to be applied to the pandemic time as well. There is a possibility to exchange of information 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.

Exchange of information between countries is ensured by the Medicrime Convention and our national law (on the basis of provisions on spontaneous exchanges of information provided by the Act XXXVIII of 1996 on the international legal assistance in criminal matters and Act CLXXX of 2012 on the judicial cooperation in criminal matters with the Member States of the European Union).

Furthermore, the common existing and fast channels of exchange of information, such as Eurojust, EJN, Interpol, work very well in the practice as well.

However, there are no national common databases or any other special channels to share information.

Detection

This section seeks to understand and appreciate the various measures that may be proactively taken during a pandemic

to detect counterfeit medical products and to prevent them from reaching

Question 23. (mandatory)

Are there legislative or other measures to ensure that industry can promptly report suspicions or detections of counterfeit medical products and similar crimes involving threats to public health, to any particular authority? Are there established or ad hoc procedures and processes for this reporting?

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.

According to Section 376(1)-(2) of CCP, any person may file a crime report regarding a criminal offence subject to public prosecution. Moreover, a member of an authority, a public officer, and, if required by law, a statutory professional body shall 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.

Question 24. (mandatory)

Is there a market sampling programme established to detect counterfeit medical products on the market? If so, which authority is responsible for this? Is this system sustainable in times of pandemic having regard to the additional demands placed on analytical laboratories and testing services by the impact of the pandemic? Are there oversight arrangements to ascertain the effectiveness of these measures?

During the pandemic primarily customs were coordinated by programs (actions) to detect counterfeit medical products with the participation of many authorities. World Customs Organisation launched Operation STOP and Operation STOP II to protect the public against counterfeit/illicit medicines and other sub-standard medical supplies and equipment in the context of the COVID-19 pandemic. The Hungarian participation was coordinated by the National Tax and Customs Administration.

Beyond the above, the Ministry for Innovation and Technology coordinated market sampling programmes.

Question 25. (mandatory)

Do these sampling programmes, mentioned in question 24 above, cover public procurement of medical products to detect counterfeit medical products being used in the public health system, such as in hospitals, and not procured for supply by sale to the trade or public? If not, are there arrangements to introduce such a programme?

Besides pharma serialisation (verification of the authenticity and identification of every individual pack of a medicinal product) which started at the EU level in 2019, there is currently no other program to detect counterfeit medical products in the public health system.

Question 26. (mandatory)

Are there laws and policies in place to enable customs services to detect, detain and act on a counterfeit medical product, as defined in Article 4.j, different to the intellectual property counterfeiting? Do the laws and policies enable customs services to take action without reference to a rights holder notwithstanding that the same medical product may also infringe an intellectual property right?

Yes, the general rules have to be applied to the pandemic time as well. Minor cases concerning counterfeiting of medicinal products fall under the competence of the National Tax and Administration Office, which investigates these infractions during an infraction procedure (Section 119/A of the Act II of 2012 on infractions, on infraction proceedings and on infraction registration system).

Section 199/A – Pharmacy infraction
(1) Any person, who
a) offers, hands over, acquires or keeps in quantities not exceeding an unjustified quantity a counterfeit or counterfeited medicinal product or veterinary medicinal product, or a medicinal product or veterinary medicinal product not licensed in Hungary,
b) keeps an unjustified quantity of a substance or preparation that qualifies as a prescription medicine in Hungary,
commits an infraction.
(2) Proceedings for an infraction under paragraph (1) shall fall within the competence of the National Tax and Customs Administration.
(3) For the purposes of paragraph (1), unjustified quantity means a quantity that is clearly not intended for the purpose of satisfying the personal needs of a specific patient.

Investigation and Prosecution

This section concerns the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a

It has to be underlined concerning all questions of this Section that general rules have to be applied to the pandemic time as well.

Question 27. (mandatory)

Please outline through the following measures how is the criminalisation of offences achieved in order to enable effective investigation and prosecution.

a. To what extent does the notion of 'medical products' in internal law fully corresponds to the definition in Article 4.a, even if the term is not specifically defined?

The definition of "medical products" in the Hungarian law complies with the definition of the Convention.

The Act C of 2012 on the Criminal Code (hereinafter: CC) establishes two separate criminal 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. Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf

1. However, Section 185/A of CC does not contain a specific definition of **"medicinal product"**, the content of this term stems from the health law in the following way.

- Section 1 point 1 of the 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 of the Act 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.

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 section (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.

2. According to Section 186(5)a) of CC, **"medical product**" means a medical device, in vitro diagnostic medical device, and investigational medicinal product (test preparation). These terms are also determined by health law.

- Section 3 (h) of the Act CLIV of 1997 on health 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.
- 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 186(5)c) of CC widens the definition and determines that medical product not licensed in Hungary also means a medical device placed on the market without conducting a conformity assessment procedure.

b. To what extent does the notion of 'counterfeiting' in internal law fully corresponds with the definition by Article 4.j as regards medical products? What steps have been taken to ensure that this has been or will be achieved?

The Hungarian 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:

- **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;

- **making a counterfeit 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.

This term is applicable for both identity and/or source.

c. Please outline what steps have been taken to ensure that offences relating to counterfeit medical products, as defined in Articles 4.a and 4.j, are criminalised in accordance with Articles 5 and 6.

The acts mentioned by Article 5 and 6 of the Convention are included in CC in the criminal offence descriptions.

1. The acts of manufacturing of counterfeits (Article 5 of the Convention) are determined by Section 185/A(1)a) and Section 186(1)a) of CC.

- According to Section 185/A(1)a) of CC, a person who counterfeits a medicinal product or veterinary medicinal product or makes a counterfeit medicinal product or veterinary medicinal product, is guilty of a felony and shall be punished by imprisonment for up to three years.

- Pursuant to Section 186(1)a) of CC, a person who counterfeits a medical product or makes a counterfeit medical product, is guilty of a felony and shall be punished by imprisonment for up to three years.

2. The acts of supplying, offering to supply, and trafficking in counterfeits (Article 6 of the Convention) are determined by Section 185/A(1) b),c) and Section 186(1) b),c) of CC.

- According to Section 185/A(1) b),c) of CC, a person who
  - places on the market, trades in, or offers, or hands over unjustified quantities of, a counterfeit or counterfeited medicinal product or veterinary medicinal product,
  - imports to, exports from, or transports through, the territory of the country, or acquires or keeps an unjustified quantity of, a counterfeit or counterfeited medicinal product or veterinary medicinal product,

  is guilty of a felony and shall be punished by imprisonment for up to three years.

- Pursuant to Section 186(1) b),c) of CC
  - offers, hands over, places on the market, or trades in, a counterfeit or counterfeited medical product,
  - imports to, exports from, or transports through the territory of the country, or acquires or keeps an unjustified quantity of a counterfeit or counterfeited medical product,

  is guilty of a felony and shall be punished by imprisonment for up to three years.

d. Please outline what steps have been taken to ensure that intentional offences described in Article 8 relating to medical products, as defined in Article 4.a, are criminalised.

The acts mentioned by Article 8 of the Convention are included in CC in the criminal offence descriptions.

I. The acts of the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of

- medicinal products without authorisation where such authorisation is required under the domestic law of the Party [Article 8 point a) i) of the Convention]; or
- medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party [Article 8 point a) ii) of the Convention]

are determined by Section 185/A(1) b),d) and (8)b) of CC and Section 186(1) b),d) and (5)c) of CC.

1. Medicinal products without authorisation where such authorisation is required under the domestic law of the Party [Article 8 point a) i) of the Convention]

- According to Section 185/A(1) b),d) of CC, a person who
  - places on the market, trades in, or offers, or hands over unjustified quantities of a medicinal product or veterinary medicinal product not licensed in Hungary,
  - acquires, keeps, imports to, exports from, or transports through, the territory of the country an unjustified quantity of a medicinal product or veterinary medicinal product not licensed in Hungary,

  is guilty of a felony and shall be punished by imprisonment for up to three years.

  According to Section 185/A(8)b) of CC, for the purpose of this section 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.

2. Medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party [Article 8 point a) ii) of the Convention]

- Pursuant to Section 186(1) b),d) of CC, a person who
  - offers, hands over, places on the market, or trades in a medical product not licensed in Hungary,
  - imports to, exports from or transports through the territory of the country, or acquires or keeps an unjustified quantity of a medical product not licensed in Hungary,

  is guilty of a felony and shall be punished by imprisonment for up to three years.

  Pursuant to Section 186 (5)c) of CC, for the purposes of this section medical product not licensed in Hungary also means a medical device placed on the market without conducting a conformity assessment procedure.

II. The acts of 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 8 point b) of the Convention] are determined by Section 185/A(1)e) of CC and Section 186(1)e) of CC.

- According to Section 185/A(1)e) of CC, a person who uses an original document pertaining to a medicinal product or veterinary medicinal product outside its intended use, for a commercial purpose, is guilty of a felony and shall be punished by imprisonment for up to three years.

- Pursuant to Section 186 (5)e) of CC, a person who uses an original document pertaining to a medical product outside its intended use, for a commercial purpose, is guilty of a felony and shall be punished by imprisonment for up to three years.

e. Please outline what steps have been taken to ensure that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products.

The CC punishes the use of false or falsified public or private deeds (Section 342(1) and 345 of CC). Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf

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."

f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)?

The Act CIV of 2001 on the criminal measures applicable against legal persons sets out the rules of the criminal liability of legal persons.

Question 28. Framework for investigation and prosecution **(mandatory)**

Please provide information, specifically in relation to counterfeit medical products and similar crimes involving threats to public health, on:

a. any national specialised investigation units dedicated to:
   1) conducting criminal investigations, and/or

There is no specialized/designated unit in this area at the police, the investigations are carried out by each police criminal services. Every county police criminal service is involved in this issue. There is a nominee at Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) at Directorate General for Criminal Investigation, 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 investigation of Section 185/A and Section 186 of CC is the responsibility of the local police departments, unless the offences cause permanent disability, serious degradation of health or death, or are committed in a criminal conspiracy, and in the case of counterfeiting of medical products, if a counterfeit or counterfeited medical product or a medical product not licensed in Hungary becomes widely available to users. In such cases, the county (capital) police headquarters are entitled to conduct the investigation. In special cases, the Airport Police Directorate also acts in these cases. *[25/2013 (VI. 24.) BM Decree of the Ministry of Interior on the powers and territorial jurisdiction of the investigative authorities of the Police, 67/2007. (XII. 28.) IRM Decree of the Ministry of Justice and Law Enforcement on determining the territorial jurisdiction of the Police bodies, 329/2007 (XII. 13.) Korm. Decree of the Government on the bodies of the Police and the duties and powers of the Police bodies]*

   2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure;

Investigations on counterfeiting of medical and medicinal products are supervised by the district prosecution offices. *[Instruction 21/2011 (XII.20.) LÜ of the Prosecutor General on the territorial jurisdiction of prosecution offices]*

b. any specialised prosecutors and whether they function on a national or local basis.

If neither a or b apply, please describe briefly the framework used for specialised investigations and prosecutions to ensure that the full understanding of the crimes involved are taken into consideration.

In general, the CCP determines the competences between police and the National Tax and Customs Administration (Section 34 of CCP). The decree of the Ministry of the Interior No 25/2013 states which police investigative body (regional or local police department) is responsible for these criminal offences. Under the general rule of jurisdiction, those police department is responsible for these criminal offences on the territory of which the offense was committed.

Question 29. (mandatory)

In relation to the investigation of counterfeit medical products and similar crimes involving a threat to public health, please indicate, without entering into detail:

a. the process in place, or planned, for deciding which investigation unit/body takes responsibility/the lead for investigations in general or as they occur;

In general, the CCP determines the competences between police and the National Tax and Customs Administration (Section 34 of CCP). The decree of the Ministry of the Interior No 25/2013 states which police investigative body (regional or local police department) is responsible for these criminal offences. Under the general rule of jurisdiction, those police department is responsible for these criminal offences on the territory of which the offense was committed.

b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3. b).

There is no special regulation concerning crimes related to a pandemic.

Question 30. (optional)

Please provide details of any dedicated facility available for the public to report information to investigating authorities (this does not relate to pharmacovigilance or product quality defect reports). Please provide details of whether the reporting is done by telephone, email, via an online platform, or other means, and whether this is a confidential report system. Is the reporting system reviewed for effectiveness? Please provide your assessment of the effectiveness of such facility.

An online reporting platform is available through police.hu, which is anonymous. In addition, police receives notifications from the public by letter and e-mail several times. Police has no information on the effectiveness of these systems.

There is a dedicated email address for the purpose to report but information may be sent in any way and all methods are accepted. Mainly the dedicated email address (hamisgyogyszer@ogyei.gov.hu) is used but there is a more confidential facility using electronic forms submitted by the official gateway.
Email communication is more effective although less confidential as reports are mostly sent via unprotected email services.

Question 31. (mandatory)

Are complaints on counterfeit medical products and similar crimes collated on a national basis for record keeping, analysis, and effective investigation or dealt with on an ad hoc basis by individual investigating authorities/bodies?

There is no central body to deal with these complaints. According to Section 376(1)-(2) of CCP, any person may file a crime report regarding a criminal offence subject to public prosecution. Moreover, a member of an authority, a public officer, and, if required by law, a statutory professional body shall 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. There is a possibility on a case by case basis to investigate on the basis of a complaint, which is investigated by the police or the prosecutor's office supervising each case.

Question 32. (mandatory)

Are all prescribed offences in Articles 5-8, and Article 9 investigated? Are they subject to a complaint being made and maintained (Article 15)?

Yes, all these criminal offences are subject to public prosecution. 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.

Chapter LVIII of CCP sets out the rules of legal remedies available during the investigation. Please see the relevant text.

Question 33. (optional)

In relation to counterfeit medical products and similar crimes involving a threat to public health, is there an indicative list of offences, associated with Articles 5-9, 11 and 13 and other criminal laws, to facilitate investigators in deciding the legal basis and the evidence required for successful investigations, in particular during a pandemic when advisory experts and technical staff may not be immediately available (Article 16)?

Until now it was not necessary to launch such an indicative list, because advisory experts gave the information for police and National Tax and Customs Administration in time.

Question 34. (optional)

Please outline the national approach with regard to investigating bodies/authorities on counterfeit medical products and similar crimes, in a manner consistent with procedural rules of internal laws, on the extent of any discretion on whether to initiate and terminate an investigation without reference to a prosecuting authority or other investigating authorities for medical product counterfeiting?

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. Furthermore, 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].

All grounds for dismissing the crime report (Section 381 of CCP) or for terminating the proceeding (Section 398 CCP) are determined by CCP.

Sanctions and aggravating circumstances

This section aims at identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating offences committed in a pandemic.

It has to be underlined concerning all questions of this Section that general rules have to be applied to the pandemic time as well.

Question 35. (mandatory)

Do internal laws permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other

instrumentalities used to commit the offences described in Articles 5-8? (Article 12. 2. a and b).

Yes. According to Section 308 and 324 of CCP, seizure or sequestration shall be ordered during the criminal proceedings. Pursuant to Section 72-76 of CC, confiscation or forfeiture of assets are mandatory to order as a measure. Please see the relevant text.

Pursuant to Section 321(3) of the Act CCXL of 2013 on the execution of punishments, measures, certain coercive measures and administrative confinement, the confiscated object shall be destroyed, if the placing on the market – among others - would endanger or violate the public order, public health, environment or public morals.

After the material is confiscated by the court, it is then possible to destroy the confiscated material. Destruction takes place in a designated incinerator, in such type of incinerator which has a proper environmental authorization.

Question 36. (optional)

Are there policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering, for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming?

It depends on the circumstances of the special case, but these kind of acts are punishable acts on the basis of fraud or other similar criminal offences, such as budget fraud or placing poor-quality products on the market.

Question 37. (optional)

Is there a policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products?

Yes, it depends on the circumstances of the special case. Usually concurrence of criminal offences can be determined, e.g. counterfeit medicines and intellectual property offenses.

Question 38. (mandatory)

Is there a specific sanctioning policy relating to offences related to counterfeit medical products and similar crimes generally, with specific reference to Article 13 circumstances in so far as they do not already form part of the constituent elements of the offence, and if so, whether the fact that the offence occurred during a pandemic is considered as an aggravating circumstance?

Most aggravating circumstances mentioned in Article 13 of the Convention are parts of the criminal offence descriptions [Section 185/A (3)-(6) and Section 186 § (2)-(4) of CC] as qualified cases, which are punishable with more severe punishment.

However, aggravating circumstances mentioned by Article 13 point e) and f) of the Convention are not part of the criminal offence descriptions. These circumstances are determined in the General Part of CC which have to be applied and taken into account for all criminal offences. It means if the perpetrator committed the criminal offence in a criminal organisation, Section 91 of CC shall be applied automatically. In this case, if a person

committed an intentional criminal offence in a criminal organisation, the maximum of the penalty range applicable to the criminal offence shall be doubled, but it shall not exceed twenty-five years.

Or if the perpetrator committed the same criminal offence or similar criminal offences both times, Section 89 of CC shall be applied automatically. According to this rule, regarding a special or multiple recidivist, 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.

Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf

Article 13 of the Convention		Criminal Code	
point a	death, damage to the physical or mental health	Section 185/A(3)	Section 186(2)
point b	abusing the confidence placed in them in their capacity as professionals	Section 184/A(5)a)	Section 186(3)a)
point c	abusing the confidence placed in them as manufacturers as well as suppliers	Section 184/A(5)b)	Section 186(3)b)
point d	large scale distribution	Section 184/A(6)	Section 186(4)
point e	criminal organisation	Section 91, Section 321	
point f	previous conviction for offences of the same nature	Section 89	

Furthermore, according to the principles of sentencing (Section 80(1) of CC), punishment shall be imposed within the framework laid down in CC, 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. It means, that the court shall take into account all the time the mitigating and aggravating circumstances.

Question 39. (optional)

Please specify if and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article13. c).

As we mentioned above, Article 13 point b) and c) of Convention are considered qualified cases in CC.

Moreover, disqualification from a profession (Section 52-53 of CC) is another punishment which can be imposed next to the imprisonment. Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf

In connection with legal persons, according to Section 3 of the Act CIV of 2001 on the criminal measures applicable against legal persons if the court imposes punishment on the person committing the criminal offence defined in Article 2 or applies reprimand or probation against this person, orders confiscation or forfeiture of assets, it may apply the following measures against the legal person:
a) winding-up the legal person,
b) limiting the activity of the legal person,
c) imposing a fine.

Data Collection

This section concerns the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

Question 40. (optional)

Please indicate whether data is collected for the purpose of observing and evaluating the phenomenon of counterfeit medical products or for another purpose (Article 17.3.a and b). Please:

a. Specify if data is collected in the normal course of activity and for what purpose.

b. Indicate whether they were collected specifically during the COVID-19 pandemic. If not, can data for the period of the pandemic be separated from that collected in the normal course of activity?

c. Specify what mechanisms have been established for data collection.

There is no special system for collecting data. Police collects every data of criminal case by own system which called RobotZsaru Neo.

d. Provide the relevant data collected, in particular that during the COVID-19 pandemic, and any reports from the analysis of this data.

e. Indicate if the data and relevant reports based on such data were shared with all the relevant authorities/bodies. Please list the authorities/bodies that compiled the data, produced the reports and those who received them.