



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.

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.

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.

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)?
- b. healthcare practitioners, police, customs, and health product regulators?
- c. specialised investigation units/bodies in the investigation of counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?

AD 1. a, b

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

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

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

Individual content can be prepared as an independent educational event, or a certain topic can be included in already established and traditional forms, e. g. in judicial schools. In the first case, of course, the financial burden is significantly higher, the concrete time for the implementation of such training takes from 4 to 6 months, in the second case, both the financial input and the preparation time are reduced, depending on which or what form of already established training a certain topic is placed in.

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

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

AD 1.c.:

As regards training there were no specific legislative and other measures taken or envisaged in the context of pandemics.

The Police, Customs, the Supreme State Prosecutor's Office of the Republic of Slovenia and JAZMP are in charge of co-operation and information exchange in the field of the MEDICRIME Convention. Training is conducted separately by individual services.

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

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?

The disposal of waste medicinal products in the Republic of Slovenia has been carried out since 2008 in accordance with the Regulation on the Management of Waste Medicinal Products (Official Gazette of the Republic of Slovenia, No. 105/08, 84/18 – ZIURKOE and 44/22 – ZVO-2), [Uredba o ravnanju z odpadnimi zdravili \(PISRS\)](#), which precisely defines the obligations of individuals, pharmacies, healthcare providers, wholesalers of medicinal products and authorized collectors of waste medicinal products. According to the regulation, waste medicinal products include unused medicinal products and medicinal product residues, including their immediate and secondary packaging.

The Ministry of the Environment is responsible for the implementation of this regulation, which is also responsible for the training of authorized collectors of waste medicines.

Regulation on the Management of Waste Medicinal Products lays down rules of conduct and conditions for the collection and disposal of medicinal products that have not been used for any reason – these medicinal products are classified as waste medicinal products that must not be disposed of together with other municipal waste but must be collected separately. Each person can return unused medicines to the pharmacy or dispose of them in special containers during take-back campaigns of unused medicines. The pharmacy, however, must hand over the discarded unusable drugs to a designated collector of waste medicines. Waste medicines collected by authorized waste collectors from pharmacies or other healthcare providers and wholesalers or collected at the time of campaigns must be handed over for destruction by incineration.

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?

The Ministry of the Environment is responsible for conducting inspections of the implementation of the Regulation on the Management of Waste Medicinal Products. This regulation includes also a waste management plan that sets out the obligations of an authorized collector of waste medicines. The collector of waste medicinal products must ensure that the disposal of waste medicinal products is carried out only by persons who have an environmental permit for waste disposal in accordance with the regulations governing waste management. The collector of waste medicinal products must keep records of the amount of waste medicinal products collected and prepare an annual report on the management of waste medicinal products taken over.

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 the Covid 19 pandemic Agency for medicinal products and medical devices of the Republic of Slovenia (JAZMP) sent a letter to Slovenian National Institute of Public Health (a governmental institution which acts as a wholesaler and supplier to health professionals for majority of vaccines) about the risk of reusing vaccine vials by criminal organizations and to establish safe waste management procedures to ensure proper storage and disposal of expired or waste vaccine vials. And to remind vaccination sites or vaccination providers that waste vaccine vials and expired vaccines awaiting destruction must be handled with special care and that a long-term storage of waste empty vials at the vaccination sites should be avoided. As well as to establish control over the delivery of waste vials to waste medicines collectors and to verify that the quantities delivered will actually be destroyed.

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;
- 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;

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

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

JAZMP has published a public notice on its website about the online purchase of medicines and all the risks to which customers are exposed. It also informs that only non-prescription medicines can be dispensed online, and only in pharmacies and specialized stores that are licensed to dispense medicines online. Customers are instructed on how to check whether online pharmacies are operating legally.

JAZMP publishes on its website also warnings about detected falsified medicines and other suspicious medical products in order to inform the public about the health risks that these products pose.

During Covid 19 pandemic JAZMP published warnings about fraudulent online offers of alleged versions of vaccines against Covid-19. The citizens were warned not to fall for false promises and not to buy vaccines online and that vaccinations can only be performed by qualified medical personnel from vaccination providers. JAZMP also informed the public with the announcements of WHO, Interpol and Europol on the disclosure of a criminal networks of counterfeiters of vaccines against Covid-19.

JAZMP does not measure the results of these measures.

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.

In accordance with the article 23 of Medicinal Product Act (Official Gazette of the Republic of Slovenia, No. 17/14, 66/19, 206/21 - ZDUPŠOP, 141/22 – ZNUNBZ) business entities involved in the marketing of medicinal products must inform JAZMP of any suspicion of falsification of the medicinal product. JAZMP evaluates the data, requests and monitors a possible recall of a medicinal product, and decides on how to inform the public about it.

In addition to stakeholders operating in the pharmaceutical supply chain, citizens are also encouraged to inform JAZMP of any inadequate quality of products or of the suspicion or discovery of falsified or unauthorized medicinal products on the market. For this purpose, more detailed instructions for identifying and reporting such cases have been published on the JAZMP website.

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.

JAZMP cooperates with the media by answering questions about medicines, including drug abuse, falsified medicines, etc. This type of cooperation was intensive during the Covid pandemic.

JAZMP also regularly cooperates with the academic sphere (Faculty of Pharmacy, Faculty of Security Sciences) in the educational process and ad hoc events, where topics related to falsified medicines are discussed, as well as with articles and publications.

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)?

On 16 June 2020, the Commissioner for Health of the European Commission (EC), Ms Stella Kyriakides addressed an invitation letter to all Ministers of Health of the Member States (hereinafter: MS) to join joint activities aimed at strengthening the negotiating power of MS at EU level in negotiations with manufacturers of promising vaccines against coronavirus disease (hereinafter: COVID-19) with the aim of achieving the lowest possible prices and other conditions, liability for damages as well as quantities of vaccines, adequate supply in sufficiently large quantities and at the most convenient timeframes, thus ensuring safe, effective COVID-19 vaccines at affordable prices and for all EU Member States in an equal and transparent manner, within the same timeframes.

Based on the positive responses to the proposed joint measures by all EU Member States, the EC published the EU Strategy for COVID-19 Vaccines (9021/2020) on its website: [EUR-Lex - 52020DC0245 - EN - EUR-Lex](#). In that strategy is included a document entitled "Advance Purchase Agreements (APAs)". The EC negotiates and contracts on behalf of the MS with the manufacturers of the most promising COVID-19 vaccines under the APAs.

In accordance with the above, the Government of the Republic of Slovenia concluded contracts for the purchase of COVID-19 vaccines with selected manufacturer and adopted a national vaccination strategy, which at the implementation level designated the National Institute of Public Health of the Republic of Slovenia for the purchasing of vaccines directly from the manufacturer, storage and distribution of vaccines to vaccination centers, the recording and collection of vaccination data, the preparation of reports on the supply, stock and consumption of vaccines on a weekly basis, informing the Ministry of Health and the Prime Minister's Office. The distribution of vaccines and the implementation of vaccinations were carried out exclusively within the framework of public health activities, thus preventing the intrusion of counterfeit vaccines.

The same procedure was taken for the supply of all medicines for the treatment of patients infected with SARS-Cov-2.

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)?

No - during the pandemic, the Government of the Republic of Slovenia supervised all procedures, from the procurement, distribution and implementation of vaccination with COVID-19 vaccines. No case of vaccination with falsified medicinal products has been recorded in the Republic of Slovenia.

In general, since the amount and the type of information and support to crime victims in pre-criminal and criminal proceedings depends on the personal characteristic and vulnerability of concrete victim (or injured party) there are no specifics needed or planned for the time of the pandemic.

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)?

There are no specific rules for times of a pandemic.

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

- free medical, psychological and other assistance and support;
- assistance and measures pursuant to the act governing the prevention of domestic violence;
- protective and other measures for ensuring personal security under this Act and the act governing the protection of witnesses;
- the rights referred to in Article 65 of this Act and the right to free legal aid under the act governing free legal aid;
- the possibilities for compensation for damages under this Act and the act governing compensation to victims of crime;
- payment and reimbursement of the costs incurred by the injured party under Article 92 of this Act;
- the right to interpretation and translation under this Act;
- the contact person of the competent authority with whom he or she can communicate about his or her case;
- any other rights or benefits that may be relevant to the injured party.

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

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

In order to ensure his or her personal security, the injured party may request to be informed of the release or escape of the suspect or accused person from house arrest or from pre-trial detention. He or she shall be informed of this right by the competent authority during the first contact in pre-trial or

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

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

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

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).

According to Paragraph 4 of Article 65 of the Criminal Procedure Act, in pre-trial and criminal proceedings, a minor as victim, an injured party who is a victim of violence or another injured party, if so required by the nature and gravity of the crime, his or her personal circumstances or the degree of threat, may be accompanied by a person of his or her choosing, except if this is contrary to the interests of a successful implementation of pre-trial or criminal proceedings or the benefit of the injured party.

The escort of the person chosen by the victim does not depend on that person's membership in any organization, NGO etc.

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.

More than 95% residents of the Republic of Slovenia have compulsory health insurance. If the victims have compulsory health insurance, their physical, psychological and social recovery

are guaranteed by the following regulations: Health Care and Health Insurance Act (ZZVZZ), Act of Patients' Rights and Act of Mental Health. For victims who do not have compulsory health insurance, the costs of treatment are provided from the budget of the Republic of Slovenia.

Consumer Protection Act Article 58 states that in accordance with the general rules on liability for damage and the rule on the liability of the manufacturer of defective goods, the manufacturer of the goods shall compensate for the damage caused by the defect in the goods when the defect in the goods causes death, bodily injury or damage to human health, or when the defect in the goods causes damage to another thing. The manufacturer shall compensate for damage to another item if the damaged item is normally intended for private use and the injured party has used it mainly for private use, in which case the injured party's deductible for the damage amounts to EUR 500. If the producer of the goods or the importer cannot be identified, any supplier of goods shall be deemed to be the manufacturer unless he informs the injured party within a reasonable period of time of who the manufacturer or importer is or which person has supplied the goods to him.

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).

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

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

According to Article 146 of the Criminal Procedure Act any person may report a criminal offence which is prosecutable *ex officio*.

Criminal complaints / report should be filed with the competent state prosecutor in writing or orally.

As we have explained to Question 11, the amount and type of information on possible protection and assistance to victims depends on the personal characteristics and vulnerability of the injured party, his or her specific needs for protection, the nature, gravity and circumstances of the crime and the stage of pre-trial or criminal proceedings.

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).

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

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

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

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

JAZMP cooperates also with the Police in case of a suspicion of a criminal offence according to the article 183 of Criminal code "Manufacturing and supply of harmful products for treatment" or article 183a

“Manufacturing and supply of counterfeit medical products, medical products without marketing authorization or medical devices that do not comply with the requirements of the Reg-MDR”.

Strategy/programme – Prevention of counterfeiting of medical devices and similar activities endangering public health is included in Resolution on the National Programme for the Prevention and Suppression of Crime 2024-2028 (ReNPPZK24-28); which states that prevention, detection and prosecution of these crimes is highly inter-ministerial and requires good cooperation between the competent authorities. They also require education, awareness, and empowerment programs for all stakeholders. It is therefore necessary to strengthen the functioning of the Inter-Ministerial Working Group of the Republic of Slovenia (Ministry of Health, Ministry of Justice of the, State Prosecutor's Office, Ministry of Internal Affairs and Police, Ministry of Finance, and Agency of the Republic of Slovenia for Medicinal Products and Medical Devices. Indicators to measure performance of named Working Group are: a preventive programme to prevent such offences, the number of inter-ministerial coordination meetings, the number of criminal offences detected and final convictions for the offences in question, the number of trainings and consultations carried out on the subject. The deadline for implementation is by the end of 2028.

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)?

Yes

- 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 was no need - please see answer to Question 5

- 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.

Regarding international cooperation in criminal matters, Slovenian criminal legislation is harmonized with conventions on international legal assistance and also includes simplified procedures.

Cooperation with the competent authorities of the EU member states is regulated by the Cooperation in criminal matters with member states of the European Union act.

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.

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.

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.

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.

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.

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?

Yes, please see answer to Questions 15 and 16.

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 patients.

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?

In accordance with the article 23 of Medicinal Product Act all stakeholders involved in the marketing of medicinal products must inform Agency for medicinal products and medical devices of the Republic of Slovenia (JAZMP) about the inadequate quality of the product or suspicion of a falsified product on the market, regardless of whether the falsified products were found in illegal or legal distribution chain. Information on what could be cases of inadequate quality or falsification, as well as instructions on how to report them, is published on the Agency's website. Reporting is possible via e-mail to a dedicated mailbox or using a 24-hour mobile phone number. All reported cases are handled by the inspector on duty 24 hours a day.

As we have already explained – any person may report a criminal offence which is prosecutable *ex officio* and all state authorities and organisations with public authority are obliged to report criminal offences which are prosecutable *ex officio* if they have been informed of them or if they have been brought to their notice in some other way.

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?

There is no sampling programme specifically designed to detect falsified medicines. However, under Article 154 of the Medicinal Products Act, medicinal products are subject to official quality control (regular and extraordinary), which is performed by Official Medicines Control Laboratory. Regular quality control is planned in advance, while extraordinary quality control is performed only on the request of a pharmaceutical inspector in the event of suspected quality defect or falsification. Both types of official quality control include analytical testing and labelling control, and the results of both types of control may indicate that falsification may be involved.

During the pandemic, the Government of the Republic of Slovenia led the supply of COVID-19 vaccines directly from manufacturers selected in the EU joint public procurement and organized the distribution and storage of vaccines and supervised vaccination. This prevented the entry of counterfeit vaccine on our market. The same applied to all medicines for the prevention and treatment of patients suffering from COVID-19.

Please see answer to Question 9.

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?

NO - The Government of the Republic of Slovenia has purchased all Covid-19 vaccines directly from the manufacturers of these vaccines, which were selected on behalf of the MS by the EC within the

framework of the joint public procurement procedure for the procurement of Covid-19 vaccines "Advance Purchase Agreements (APAs)".
Please see answer to Question 9.

All authorized medicinal products are subject to national official quality control, whether or not they are used in hospitals or in public pharmacies, except medicinal products that have obtained marketing authorization according to centralized procedure, which are sampled and tested according to the CAP Sampling & Testing Programme, performed by EMA and EDQM.

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

Customs may take actions in case of counterfeited medicines when there is an infringement of intellectual property rights in accordance with Regulation 608/2013 on the enforcement of intellectual property rights by customs authorities (OJ EU L 181).

In addition, there is a complete prohibition of the import of medicines from third countries by individuals (except in personal luggage carried by passenger). Therefore, most medicines from third countries in postal or express courier shipments are rejected – import is not allowed, and the shipments are returned to the sender).

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 pandemic.

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?

Legislation that we apply at national level for medicinal products and medical devices does not define the term "medical product" in the way it is in the MEDICRIME Convention. In national legislation, the definitions "medicinal product" and "medical devices" are understood and used as a common term for "medical product" which include both drugs and medical devices and documentation. The term "medical product" is used in Resolution on the national program for the prevention and suppression of crime 2019–2023 (ReNPPZK19–23).

Article 183.a of the Criminal Code (KZ-1), which implements the Convention, criminalizes manufacturing, preparation, production, selling or offering for sale or buying or storing for the purpose of sale or putting on the market, or serving as an agent in the sale or purchase, importing or exporting,

inputting or outputting or otherwise putting on the market medicinal products, as well as medical devices that are counterfeited/falsified.

- b. 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?

By ZZdr-2 definition of "falsified medicinal product" is any medicinal product with false presentation of:

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

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

By the European Parliament and of the Council of 5 April 2017 on medical devices (Reg-MDR). definition of 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its t include unintentional non-compliance and is without prejudice to infringements of intellectual property rights

- 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.

Criminal Code was amended with **the new Article 183.a (criminal offence of "Manufacture and trade in counterfeit medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements")**:

"1) Whoever manufactures, prepares, produces, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or serves as an agent in the sale or purchase, imports or exports, inputs or outputs or otherwise puts on the market medicinal products, active substances, excipients, medical devices or their parts or accessories or other healing remedies that are counterfeited, and has not committed a more serious criminal offence according to this Code, shall be sentenced to imprisonment for not more than five years.

(2) Whoever commits an offence referred to in the preceding paragraph with medicinal products without marketing authorisation, or with medical devices that do not meet compliance requirements shall be punished to the same extent.

(3) If an offence referred to in paragraph one or two of this Act is committed by a person who abused the trust placed in him or her, the perpetrator shall be sentenced to imprisonment between one and five years.

(4) Medicinal products, active substances, excipients, medical devices, their parts, accessories or other means of treatment referred to in paragraphs one and two of this Article shall be confiscated."

- 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.

At the same time as the addition of new Article 183.a of the Criminal Code also a criminal offence of **"Manufacture and trade in harmful medical products" (Article 183 of the Criminal Code)** was amended to read as follows:

“(1) Whoever manufactures, prepares, produces, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or mediates in the sale or purchase, imports or exports, introduces or removes or otherwise puts on the market medicinal products, active substances, excipients, medical devices or their parts or accessories or other healing remedies that are harmful to health shall be sentenced to imprisonment between one and eight years.

(2) Whoever extracts, prepares, produces, processes, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or serves as an agent in the sale or purchase, imports or exports, introduces or removes or otherwise puts on the market infected blood or other tissue or a medical remedy produced on the basis thereof shall be punished to the same extent.”.

(3) Whoever commits the offence referred to in paragraphs one or two of this Article out of negligence shall be sentenced to imprisonment for not more than one year.

(4) If the commission of an offence referred to in paragraph one, two or three of this Article results in a serious or a particularly serious bodily injury or in a corresponding impairment of health of at least one person, or if the offence was committed by a person who abused the trust placed in him or her, the perpetrator shall be sentenced to imprisonment between one and ten years for the offence referred to in paragraph one or two of this Article, and for not more than five years for an offence referred to in the preceding paragraph.

(5) If the offence referred to in paragraphs one, two or three of this Article results in the death of one or more persons, the perpetrator shall be sentenced to imprisonment between two and fifteen years for committing the offence referred to in paragraphs one or two and between one and ten years for committing the offence referred to in paragraph three.

(6) Harmful medicinal products, active substances, excipients, medical devices, their parts, accessories or other means of treatment, infected blood, other tissue or a medical remedy produced on the basis thereof shall be confiscated.”.

- 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.

Criminal offences were already determined before the implementation of the Convention – therefore no amendments needed:

- criminal offence of defrauding of customers (Article 232 of the Criminal Code);
- criminal offence of unauthorised use of another’s mark or model (Article 233 of the Criminal Code);
- criminal offence of forging of documents (Article 251 of the Criminal Code)

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

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

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

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

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

(1) Under the conditions referred to in the preceding Article, a legal person shall also be liable for a criminal offence if the perpetrator is not found guilty of the criminal offence or if the act was committed under duress or threat from the legal person.

(2) The liability of a legal person does not preclude the criminal liability of natural persons or responsible persons for the criminal offence committed.

(3) A legal person may only be liable for criminal offences committed out of negligence under the conditions referred to in point 4 of Article 4 of this Act. In such case, the legal person may receive a lenient sentence.

(4) If a legal person has no other body besides the perpetrator who could lead or supervise the perpetrator, the legal person shall be liable for the criminal offence committed within the limits of the perpetrator's guilt.

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

Criminal acts within the scope of the MEDICRIME Convention are addressed by the locally competent Criminal Police Divisions and Police Stations of individual police departments. Work in this area is

directed and coordinated at the Criminal Police Directorate of the General Police Directorate, whereby it cooperates with representatives of the Ministry of Health, the Public Agency for Medicinal Products and Medical Devices, the Administration for Food Safety, Veterinary and Plant Protection and the Financial Administration of the Republic of Slovenia on the basis of Article 145 of the Criminal Procedure Code. In their work, criminal investigators cooperate with the locally competent prosecutor's offices in accordance with the provisions of the Criminal Procedure Act, which are also responsible for directing pre-trial proceedings

In the Criminal Police Divisions, criminalists are in charge of their fields of work, who in their work encounter criminal offences against human health referred to in Chapter 20 of the Criminal Code-1, which also criminalises the criminal offences of Production and Trafficking of Harmful Medicinal Products under Article 183, Production and Trafficking of Counterfeit Medicinal Products, Medicinal Products That Do Not Have a Marketing Authorisation, or medical devices that do not meet the compliance requirements under Article 183a and Manufacture and Trade of Harmful Foods and Other Products under Article 184 of the Criminal Code -1.

These criminal acts are also addressed by criminalists who are in charge of Chapter Twenty-Four of the Criminal Code -1, namely for crimes against the economy, in which the criminal offenses of Deceiving Customers under Article 232 and Unauthorized Use of a Foreign Designation or Model under Article 233 of the Criminal Code - 1 are incriminating.

The legal framework of the state prosecutor's offices does not provide for a specific specialization for the prosecution of crimes falling under the auspices of the Medicrime Convention. However, in practice some district state prosecuton's offices may have, within their annual work schedules, designated a particular state prosecutor who deals with referred criminal acts. Those state prosecutors operate on a local level. The pandemic hasn't any impact on this organization arrangement.

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;
- 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).

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

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

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

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

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

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.

According to Criminal Procedure Act, any person may report a criminal offence which is prosecutable *ex officio* to the competent state prosecutor in writing or orally.

Even more – Criminal Code, Article 280 determines a criminal offence of “Failure to inform authorities of preparations of criminal offence” as follows: “Anyone who knows that an offence is being prepared for which the law is punishable by imprisonment for three years or more, but fails to report it at a time when it was preventable and the act was attempted or completed, shall be punished by imprisonment for a term not exceeding one year

If the act referred to in the preceding paragraph was a criminal offence punishable by law to at least fifteen years' imprisonment or life imprisonment, the offender shall be punished by imprisonment for a term not exceeding three years.

A person who fails to report that an offence referred to in the first paragraph of this Article is being prepared shall not be punished if the offender is a spouse, a person with whom he/she lives in a cohabiting union or a registered same-sex partnership, a blood relative in the direct line, a brother or sister, an adoptive parent or an adopted child. If any of the persons referred to in this paragraph is not punished for the dismissal of the complaint referred to in the first paragraph of this Article, neither his spouse or the person with whom he or she lives in an extramarital union, nor the partner of a registered same-sex partner shall be punished for the dismissal of the complaint.”

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?

The police record the criminal acts in question in their statistical overviews according to the classification of the crime. It provides annual statistical reports on the state of criminal offences in the field of trafficking in medicinal products and the cases dealt with, which provide a detailed overview of the number of cases and seized items. It publishes its statistical reports on the Police website, where they are publicly available. For the purposes of research and analysis, the Police shall also provide such information to eligible institutions.

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)?

For the purpose of implementing the Medicrime Convention and in order to enable faster and more effective prosecution of offenders, Article 183 of the Criminal Code (KZ-1) was amended in November 2021 and a new Article 183a of the CC-1 was added.

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)?

Regarding State Prosecution, a special indicative list of offences does not exist. This applies in general as during pandemics.

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?

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.

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).

Both natural and legal persons can be deprived of illegal property benefits and objects can be seized in accordance with Criminal Code -1:

- Article 73 states that for criminal offences committed by legal persons, in addition to the safety measure of the confiscation of items in accordance with Article 73 of the Criminal Code, the following may also be imposed as a safety measure:
 - publication of the judgement,
 - prohibition of the legal person performing a specific commercial activity.
- Article 183.a in paragraph (1)., (2) and (4) states that whoever manufactures, prepares, manufactures, sells or offers for sale or for sale or placing on the market buys or feeds, or intermediates in the sale or purchase, imports or exports, introduces or exports or otherwise places on the market medicinal products, active substances, excipients, medical devices or their parts or additives or other means of treatment that are counterfeit, and no more serious offence under this Code is punishable by imprisonment for not more than five years. The same penalty shall apply to anyone who commits the act referred to in the preceding paragraph with medicinal products which are not authorized for marketing or with medical devices which do not comply with the requirements for conformity. Medicinal products, active substances, excipients, medical devices, their parts, additives or other therapeutic agents referred to in the first and second paragraphs of this Article shall be taken.

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?

No

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

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?

The reason is that Criminal Code-1 also prescribes a criminal offence of manufacture and trade in harmful medical products (Article 183 of the Criminal Code) with special aggravating circumstances of a serious or a particularly serious bodily injury or in a corresponding impairment of health of at least one person or death of one or more persons.

In criminal offence of "manufacture and trade in counterfeit medical products, medicinal products without marketing authorisation, or medical devices that do not meet compliance requirements" (Article

183.a of the Criminal Code) only one special aggravating circumstance is determined – i.e. the offence was committed by a person who abused the trust placed in him or her. The principal criminal offence (Whoever manufactures, prepares, produces, sells or offers for sale or buys or stores for the purpose of sale or putting on the market, or serves as an agent in the sale or purchase, imports or exports, inputs or outputs or otherwise puts on the market medicinal products, active substances, excipients, medical devices or their parts or accessories or other healing remedies that are counterfeited) exists only if a perpetrator has not committed a more serious criminal offence according to this Code.

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 (Article 13. c).

Criminal Code-1, Article 69 states that the following security measures may be imposed on criminals:

- 1) compulsory psychiatric treatment and care in a health institution,
- 2) mandatory psychiatric treatment at large,
- 3) **disqualification from practicing a profession,**
- 4) the prohibition of approaching or communicating with the victim,
- 5) withdrawal of a driving licence and
- 6) Confiscation of objects.

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.

Data is collected in the normal course of activity

- 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?

No

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

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

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- 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.

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