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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

medicrime@coe.int

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)?

Agency for medicinal products and medical devices organizes regular trainings about preventing and detecting falsified medical products for wholesalers and distributors, and also healthcare practitioners.
For police and customs trainings are planned (Strategic plan 2022. – 2024.) and will be organized in the coming period in accordance with the signed Agreement on Cooperation with the Ministry of Interior.
Customs Administration organises two rounds of training per year for customs officers with the right-holders as speakers. There is no specialised training with the representatives of the pharma sector but they are always active and participate.

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)?

There are no such monitoring programs yet, but after one year of training for the police and customs, an assessment of the effectiveness of the training will be made.

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?

Ordinance on medical waste management and Instructions on handling with waste generated in the provision of health care, responsibilities and obligation of all parties involved are determined.
According to the Ordinance, the producer of medical waste must collect medical waste separately, store in appropriate containers and temporarily store in a separate room until processing or handing over to an authorized person who has a prescribed license for medical management waste and keep records. Authorized person for collection and transport of medical waste must have a contract for the collection of collected waste with an authorized person for treatment, recovery and / or disposal of medical waste.
Customs Administration did not have (in the last 5 years) cases of shipments containing medicines and medicinal products suspected to infringe IPRs of the brands from pharmaceutical industry sector and thus there were no reflections on the waste management.
There are no awareness-raising campaigns organized for persons and entities responsible for cleaning and waste disposal regarding recycling of medical 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?

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.

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.

The Agency for Medicinal Products and Medical Devices continuously conducts awareness rising activities on dangers posed by counterfeit medicines and risks of buying counterfeits online. Extensive content aimed at educating public on these topics is published on the Agency's website. In addition, the Agency publishes a number of news relating to MEDICRIME convention and counterfeit medicines, including the news on Pangea operations, suspected counterfeits, as well as recommendations and guidelines from relevant bodies. These texts are in addition distributed via newsletter and are sent for publication in specialized publications for healthcare professionals. Recognising the importance of this topic, counterfeit medical products are regularly represented at the Agency's conferences.

The Agency puts particular focus on providing information on these topics to media representatives, given the importance of their role in informing the general public. The Agency regularly provides responses to media inquiries and gives TV and radio statements on counterfeit medical products. When responding to media queries, the Agency always includes a comprehensive overview of this area, with highlighted key messages and data, as well as examples and details that vividly explain the need for raising public awareness on these dangers. Positive feedback is regularly obtained from media representatives as this approach increases their understanding of counterfeit medical products, while at the same time the information delivered by the Agency is easily adapted to media format, which facilitates and encourages their publication in a greater measure.

These topics have been additionally recognised during the COVID-19 pandemic, whereby the Agency maintained its previously established approach.

Customs Administration and Ageny for Medicinal Products and Medical Devices participated at several public awareness events "Stop krivotvorinama i piratstvu" ("Stop counterfeiting and piracy"), organised by the State Intellectual Property Office where counterfeit medicines from earlier IPR infringement cases were presented (among products from all industry sectors) with an aim to present health related risks of the use of counterfeit medicines.

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

Systematic media monitoring shows that a significant number of articles about counterfeit medical products and the threat of buying medicines on the internet are published in print publications, as well as on news portals, based on the information the Agency provides. Likewise, national TV and radio stations regularly include reports on dangers of counterfeit medical products in collaboration with the Agency. One example of media reporting can be found in the attachment.

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.

State Intellectual Property Office encourages this involvement through its activities, which include public awareness events “Stop krivotvorinama i piratstvu” (“Stop counterfeiting and piracy”), aimed at presenting health related risks of the use of counterfeit medicines.

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.

There are associations involved in raising public awareness of the risks arising from counterfeit products, including medical products. One example would be Brand owners association BOA. Since its establishment in 2009, BOA has organized several events together with the Customs Administration of the Republic of Croatia, and the Customs Administration on raising public awareness among consumers.

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)?

MEDICINAL PRODUCTS ACT
Article 183
(1) Medicinal products referred to in Article 106, paragraph 2, subparagraphs 1 and 2, of this Act may be advertised in scientific literature, at symposia and conferences and to healthcare
professionals.
(2) Medicinal products referred to in Article 106, paragraph 2, subparagraph 2, of this Act
may be advertised to the public.
(3) The advertising of medicinal products referred to in Article 106, paragraph 2, subparagraph 1, of this Act to the public shall be prohibited.
(4) The prohibition contained in paragraph 3 of this Article shall not apply to public health
campaigns for the promotion of vaccination, seroprophylaxis and chemoprophylaxis

programmes drawn by the Minister in accordance with the Act on the Protection of the Population against Communicable Diseases.
(5) The advertising of any medicinal product unauthorised in the Republic of Croatia, except at symposia and conferences and in scientific literature and provided that the procedure for
granting of the marketing authorisation pursuant to this Act has been instituted and that only common name of the medicinal product is used, without any mentioning of the manufacturer, shall be prohibited.
(6) Restrictions from paragraph 5 of this Article shall not apply to scientific and expert meetings held in the Republic of Croatia.

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)?
According to the provisions of the Criminal Procedure Act (OG 152/08, 76/09, 80/11, 121/11, 91/12, 143/12, 56/13, 145/13, 152/14, 70/17, 126 / 19, 126/19), the victim of a criminal offense has in accordance with the Law:

1) the right to access services for the support of victims of criminal offenses,
2) the right to effective psychological and other professional assistance and support from a body, organization or institution for assistance to victims of criminal offenses in accordance with the law,
3) the right to protection from intimidation and retaliation,
4) the right to protection of dignity during the examination of the victim as a witness,
5) the right to be heard without undue delay after the filing of a criminal report and for further hearings to be conducted only to the extent necessary for the purposes of criminal proceedings,
6) the right to accompany a person of trust in taking actions in which he / she participates,
7) the right to have medical procedures performed on the victim to the least extent and only if they are absolutely necessary for the purposes of criminal proceedings,
8) the right to file a motion for prosecution and a private lawsuit in accordance with the provisions of the Criminal Code, the right to participate in criminal proceedings as an injured party, the right to be informed of the rejection of a criminal report (Article 206, paragraph 3 of this Act) and the right to take over prosecution instead of the state attorney,
9) the right to be notified by the State Attorney of the actions taken regarding her application (Article 206a of this Act) and to submit a complaint to the Senior State Attorney (Article 206b of this Act),

10) the right, at her request, to be informed without undue delay of the termination of custody or pre-trial detention, the escape of the defendant and the release of a convict from serving a prison sentence, and the measures taken to protect her,
11) the right to be informed at her request of any decision terminating criminal proceedings,
12) other rights prescribed by law.

(2) The victim of a criminal offense for which a prison sentence of more than five years is prescribed, if he suffers the more serious consequences of the criminal offense, shall be entitled to professional assistance of counselors at the expense of budgetary funds when submitting a property claim.
(3) The victim of a criminal offense of violence committed with intent is entitled to financial compensation from the state budget in accordance with a special law. If the victim has previously obtained a property claim, its amount will be taken into account when determining the monetary compensation, and the court will do the same when awarding the property claim if the victim has previously obtained a financial compensation from the state budget.
(4) The court, the state attorney's office, the investigator and the police shall, upon taking the first action in which they participate, inform the victim in a manner understandable to him:
1) on the rights referred to in paragraphs 1, 2 and 3 of this Article and Article 44 of this Act
2) on the rights he has as an injured party.
(5) The bodies referred to in paragraph 4 of this Article shall treat the victim with consideration and ensure that the victim understands the given notification of rights.
(6) The bodies referred to in paragraph 4 of this Article shall inform the victim in a manner comprehensible to him / her of the meaning of participation in the proceedings in the capacity of the injured party. The record shall include a notice given and a statement by the victim as to whether he or she wishes to participate in the proceedings as an injured party.

When the public prosecutor or the court informs the victim that he can take or continue the persecution, he will also provide her with instructions on what actions he can take in order to exercise that right and for that purpose provide him with access to the file.
The victim, the injured party and their attorney have the right to inspect the file. If an earlier inspection of the file would affect the testimony of the victim and the injured party, they acquire the right to inspect the file after they have been examined.

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)?

According to the provisions of the Criminal Procedure Act (OG No 152/08, 76/09, 80/11, 121/11, 91/12, 143/12, 56/13, 145/13, 152/14, 70/17, 126 / 19 and 126/19), the police, the investigator, the State Attorney's Office and the court treat the victim of a criminal offense with special regard. These bodies are obliged to inform the victim and the injured party of their rights in the proceedings in accordance with this Act and to take appropriate care of their rights when taking action.

The victim of a criminal offense has, in accordance with the Law:
1) the right to access services for the support of victims of criminal offenses,

2) the right to effective psychological and other professional assistance and support from a body, organization or institution for assistance to victims of criminal offenses in accordance with the law,
3) the right to protection from intimidation and retaliation,
4) the right to protection of dignity during the examination of the victim as a witness,
5) the right to be heard without undue delay after the filing of a criminal report and for further hearings to be conducted only to the extent necessary for the purposes of criminal proceedings,
6) the right to accompany a person of trust in taking actions in which he / she participates,
7) the right to have medical procedures performed on the victim to the least extent and only if they are absolutely necessary for the purposes of criminal proceedings,
8) the right to file a motion for prosecution and a private lawsuit in accordance with the provisions of the Criminal Code, the right to participate in criminal proceedings as an injured party, the right to be informed of the rejection of a criminal report (Article 206, paragraph 3 of this Act) and the right to take over prosecution instead of the state attorney,
9) the right to be notified by the State Attorney of the actions taken regarding her application (Article 206a of this Act) and to submit a complaint to the Senior State Attorney (Article 206b of this Act),
10) the right, at her request, to be informed without undue delay of the termination of custody or pre-trial detention, the escape of the defendant and the release of a convict from serving a prison sentence, and the measures taken to protect her,
11) the right to be informed at her request of any decision terminating criminal proceedings,
12) other rights prescribed by law.

(1) A victim of a criminal offense punishable by imprisonment for a term exceeding five years, if he suffers the more serious consequences of a criminal offense, shall be entitled to professional assistance of counselors at the expense of budgetary funds when submitting a property claim.
(2) The victim of a criminal offense of violence committed with intent is entitled to financial compensation from the state budget in accordance with a special law. If the victim has previously obtained a property claim, its amount will be taken into account when determining the monetary compensation, and the court will do the same when awarding the property claim if the victim has previously obtained a financial compensation from the state budget.
(3) The court, the state attorney's office, the investigator and the police shall be obliged to inform the victim in a manner understandable to him / her when taking the first action in which he / she participates:
1) on the rights referred to in paragraphs 1, 2 and 3 of this Article and Article 44 of this Act
2) on the rights he has as an injured party.

Article 206a

(1) The victim and the injured party have the right to request a notification from the state attorney on the actions taken in connection with the criminal report or notification of the committed offense after the expiration of two months from the submission of the criminal report or report on the committed act. The State Attorney shall inform them of the actions taken within a reasonable time, and no later than thirty days from the receipt of the request, except when this would jeopardize the effectiveness of the proceedings. He is obliged to inform the victim and the injured party who requested the notification about the denial of the notification.

(2) If the state attorney has not informed the victim or the injured party or they are not satisfied with the given notification or the actions taken, they have the right to complain to the senior state attorney.
(3) The Senior State Attorney shall verify the allegations of the complaint and if he finds that the complaint is founded, he shall order the lower State Attorney to submit the requested notification to the complainant on the actions taken or to take the actions to be taken within a reasonable time. If the Senior State Attorney finds that the lower State Attorney's actions have violated the complainant's rights, he shall inform him thereof, stating exactly the rights that have been violated.
(4) The victim and the injured party may request the notice of actions taken from paragraph 1 of this Article again after six months from the previously requested notice of actions taken, unless they have addressed a complaint to the senior state attorney referred to in Article 206b paragraph 2 of this Act. .

Article 206b
(1) The State Attorney shall be obliged to make a decision on the criminal report within six months from the day of entry of the report in the register of criminal reports and to inform the applicant thereof, stating the short reasons for that decision.
(2) After the expiry of the time limit referred to in paragraph 1 of this Article or after the expiration of six months after the State Attorney acted pursuant to Article 205, paragraph 6 of this Act, the applicant, injured party and victim may file a complaint to the senior State Attorney. lead to delays in the proceedings.
(3) The Senior State Attorney shall, after receiving the complaint referred to in paragraph 2 of this Article, request a statement on the allegations of the complaint without delay.
(4) The Senior State Attorney shall, if he assesses that the complaint is founded, determine an appropriate deadline within which a decision on the application must be made.
(5) The senior state attorney is obliged to inform the complainant about the action taken within fifteen days from the day of receipt of the complaint.
(6) The complainant may repeat the complaint if the application has not been resolved within the time limit specified in paragraph 4 of this Article.

Article 205
(1) The application shall be submitted to the competent state attorney in writing, orally or by other means.
(2) If the application is submitted orally, the applicant shall be warned of the consequences of false reporting. A record shall be made of the oral application, and if the application is communicated by telephone or other telecommunication device, its electronic record shall be provided, where possible, and an official note shall be drawn up.
(3) If the criminal report was filed by the victim, it shall be confirmed in writing that he / she has filed the criminal report with an indication of the basic data on the reported criminal offense. If the victim does not speak or understand the language of the competent authority, he or she will be allowed to file a criminal complaint in a language he or she understands with the help of an interpreter or other person who speaks and understands the language of the competent authority and the language used by the victim. At the request of a victim who does not speak or understand a language used by the competent authority, a written confirmation of the criminal complaint filed shall be transferred to the budget in a language that the victim understands.

(4) If the report has been submitted to a court, the police or an incompetent state attorney, they shall receive the report and immediately submit it to the competent state attorney.
(5) The State Attorney shall enter the criminal report in the register of criminal reports as soon as it has been filed, except in the case referred to in paragraphs 6 and 7 of this Article.
(6) If the State Attorney has only received word that a criminal offense has been committed or has received a report from the victim, the State Attorney shall draw up an official note which shall be entered in the register of various criminal cases and proceed in the manner prescribed in Article 206, paragraph 4. of this Act.
(7) If the criminal report does not contain information on the criminal offense, ie if the State Attorney cannot conclude from the criminal report for which criminal offense the report is filed, he shall enter it in the register of various criminal cases and shall invite the applicant to correct and supplement the criminal report.
(8) If the applicant does not comply with the invitation for correction or amendment, the State Attorney shall draw up a note to that effect. The senior state attorney shall be notified thereof within eight days from the expiration of the deadline for correction or amendment of the criminal report, who may order the entry of the criminal report in the register of criminal reports.
(9) The Minister in charge of justice shall prescribe the manner of keeping the register of criminal reports and various criminal cases.

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).

Ministry of Justice and Public Administration RoC:
Service for Victim and Witness Support - Central body for coordination of development of victim and witness support system

1. Provision of information to victims about the release of the offender from the prison:
- information about the regular or conditional release of the prisoner
- provision of additional support in cooperation with other relevant organizations and institutions (police, social services, probation offices, prisons, civil society organisations)

2. Provision of information and support to victims and witnesses:
- information about the rights in written form (informative letter) sent to victims and witnesses that are summoned over the mutual international legal assistance (Croatian citizens who are summoned to testify abroad and foreign witnesses summoned to testify in Croatia)
- information and support provided over the phone, referral to other relevant services

3. Provision of compensation to victims:
- administering professional, administrative and technical tasks for the Committee on compensation to crime victims, according to Act on monetary compensation for victims of criminal offences

- the victim may exercise his/her right to compensation for the cost for medical treatment, loss of earnings up to the amount of kn 35.000,00, close blood relatives of a deceased victim is entitled to compensation for loss of statutory maintenance of up to kn 70.000,00, for funeral expenses up to the amount of kn 5.000,00

II Courts
Victim and Witness Support Departments at the courts

- *There are 7 Victim and Witness Support Departments at the courts (County courts in Zagreb, Osijek, Sisak, Vukovar, Zadar, Split i Rijeka).*
- *Support Departments provide emotional support, practical information and information about rights to victims and witnesses. They provide support from the investigation phase till the end of court procedure.*
- *They provide support also at Municipal courts and their Misdemeanour departments (for domestic abuse).*

4. Financial support to NGO's

a) Programme "The Network of support and cooperation for victims and witnesses of criminal offences" that is created with the intent of providing assistance and support for victims and witnesses of criminal offences in 13 Counties in Croatia, where victim and witness support departments have not been established.

b) Civil society organizations from the Network provide support to victims and witnesses of crimes and misdemeanours. They provide information on rights, emotional support, psychological and legal counselling and, as a person of trust, provide escort to competent courts and other relevant institutions in in their counties

c) National Call Centre for Victims of Crime – NPC 116 006 - an anonymous and toll-free number which provides emotional support, legal and practical information to victims, witnesses and their family members. The service is available in both, English and Croatian, 24/7

5. Coordination of the National Committee for Monitoring and Development of Victim and Witness Support System
- members of the National Committee are representatives of: Ministry of Interior (the police), Ministry of Labour, Pension System, Family and Social Policy (social welfare), Ministry of war veterans; representatives of the State Attorney's Office, The Government's Office for Human Rights; Civil society organisation's representatives and independent professionals.
- National Committee delivered National strategy for Victim and Witness Support 2016-2020 and Action plan

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.

The Network of Support and Co-operation for Victims and Witnesses of Criminal Offences is a network of 11 civil society organizations which provide assistance and support for victims and witnesses of criminal offences (and misdemeanor offences of domestic violence) from the territory of 13 counties where Victim and Witness Support Departments were not established. Network members participated in numerous educations and thematic lectures with the aim of improving knowledge and strengthen their capacity to provide support and assistance to victims and witnesses. All members of the Network are continuously participating in educational activities with the aim of providing the highest quality services to victims and witnesses. Coordinator of the Network, Women's Room and member organization, Victim and Witness Support Service are members of Victim Support Europe, leading European umbrella organization advocating on behalf of all victims of crime, no matter what the crime, no matter who the victim is.
More information on the Network is available at https://mrezapodrskeisuradnje.com/en/o-mrezi/.

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 Ministry of Justice and Administration has a leading role in the institutionalization of the victim and witness support system within the judiciary, and coordinates the victim and witness support system in the Republic of Croatia.
Among other measures in place, it is worth highlighting the National Call Center, which provides a free service: inform victims of their rights and ways of their realization, emotional support, and refer victims to other institutions and organizations that can provide them with professional assistance. National Call Center for Victims of Crime and Misdemeanors 116 006 is available for the entire territory of the Republic of Croatia every working day from 08:00 to 20:00.
More information on the Centre is available at https://pzs.hr/en/national-call-center-for-victims-of-crime/.

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).

Cooperation and information sharing between public authorities/bodies is mandatory pursuant the Article 8(1) of the Law on the state administration system.
29th March 2021. Agency for medicinal products and medical devices signed a Cooperation agreement in the field of the fight against falsified medicines and medical devices with Ministry of Internal Affairs. In this agreement information exchange procedures are described.

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)?
Currently, implementation of national strategies and action plans is not supported by specific enabling legislation. In fact, transfer and receipt of information and data between authorities/bodies to and from other jurisdiction is primarily based on agreements.
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?
At national level, in combating counterfeit medicinal products and medical devices, HALMED shares information with Ministry of Internal Affairs and Ministry of Finance, Customs Administration, based on agreements. At international level, HALMED exchanges information within several networks, as described in reply to Question 21.

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.

Based on the Cooperation agreement in the field of the fight against falsified medicines and medical devices HALMED and Ministry of Internal Affairs will hold regular meetings at least twice a year for the purpose of informing and planning further activities.

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.

Regarding the cooperation arrangements, lead roles lie within the Ministry of Internal Affairs or Customs Administration of the Ministry of Finance. Both the Ministry of Internal Affairs and Customs act as enforcement bodies, whilst HALMED gives support in gathering information on counterfeits, cooperates in analysis and quality control of suspected products and shares information on medical products.

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.

For the purpose of expanding the system of support for victims and witnesses and providing support to citizens throughout the Republic of Croatia, the Ministry of Justice prompted the establishment and financing of activities of a partner network of organizations for support and assistance to victims and witnesses "Network of support and cooperation for victims and witnesses of crimes". Network is funded from the resources of the games of chance, based on a public tender conducted by the Ministry of Justice and Administration. Organizations involved in the Network provide information on rights, emotional support, psychological and legal counseling and, as a person of trust, provide escort to competent courts and other relevant institutions in counties in which there are no established departments for support for victims and witnesses.
More about the Network is available in response to Q13.

The Croatian Medicines Verification Organisation (HOPAL) is a non-profit organisation representing the different stakeholders, both pharmaceutical manufacturers and distribution stakeholders, involved in securing the legal supply chain from falsified medicines in Croatia. The HOPAL is responsible for implementing and managing the Medicines Verification System in Croatia.
HOPAL was established on 20 July 2017 by full members – Pharmaceutical Industry Association at the Croatian Employer's Association, Wholesale Trade Association at the Croatian Chamber of Economy and the Innovative Pharmaceutical Initiative, and as an active member – Croatian Chamber of Pharmacists.
More information is available at https://hopal.hr/en/home-page/.

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.

Representatives of national authorities/bodies are point of contacts for the international exchange of information within the WGEO and EDQM SPOC network, as well as the WHO Global Focal Point Network for substandard and falsified (SF) medical products. Furthermore, on national level HALMED, Ministry of Internal Affairs and Customs Administration of the Ministry of Finance are dedicated to combating counterfeit medicinal products and medical devices.
Except HALMED, none of the mentioned national authorities/bodies are 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.

Yes, agreements specify the point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities/bodies. Currently, it is only specified in Cooperation agreement in the field of the fight against falsified medicines and medical devices between HALMED and Ministry of Internal Affairs that the effectiveness will be discussed on regular meetings.

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.

Agency for Medicinal Products and Medical Devices (HALMED) has defined point of contacts for the international exchange of information within the WGEO SPOC and EDQM SPOC network, as well as the Rapid Alert network defined in the Compilation of Community Procedures on Inspections and Exchange of Information issued by the European Commission.
Besides the mentioned point of contacts, there are no other different or specific arrangements in HALMED for the international exchange of information related to the counterfeiting of medical products.
Moreover, HALMED's employees are included as National Focal Points to the WHO Global Focal Point Network for substandard and falsified (SF) medical products.

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. According to the legislation provisions, Agency for Medicinal Products and Medical Devices (HALMED) is obliged to exchange information on quality defects, GMP non-compliances and suspicions of counterfeiting of a medicinal product with other Member States, as well as other countries and organisations on the Rapid Alert/WGEO or EDQM SPOC list. Procedures from the Compilation of Community Procedures on Inspections and Exchange of Information are implemented in the HALMED's quality system and followed.

Legislation:
- Ordinance on the Suspension of the Placement on and Withdrawal of Medicinal Products from the Market (Official Gazette No. 122/14) defines that the Agency shall inform other European Union Member States pursuant to the Compilation of Community Procedures on Inspections and Exchange of Information on quality defects Class I and Class II and suspicions of counterfeiting of a medicinal product that could seriously threaten human health (Articles 14 and 15).
- The following Ordinances define that in performing of supervision/GMP inspections the Agency inspection shall take into consideration the Compilation of Community Procedures on Inspections and Exchange of Information, issued by the European Commission (e.g. related to the GMP non-compliances):
- Ordinance on the Conditions for Issuing Manufacturing Authorisations, on the Requirements of Good Manufacturing Practice and on the Certificate of Good Manufacturing Practice for Medicinal Products (Official Gazette No. 83/13 and 32/21) (Article 36),
- Ordinance on the Requirements and Method of Establishing the Requirements of Good Manufacturing Practice and Good Practice in the Wholesale of Active Substances and on the Procedure of the Entry in the Register of Manufacturers, Importers and Wholesalers of Active Substances, and on Issuing the Certificate for the Implementation of Good Manufacturing Practice (Official Gazette No. 83/13 and 32/21) (Articles 33 and 43).

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?

Yes, Customs Administration uses IP Enforcement Portal (EU level data exchange system managed by EUIPO) where representatives of the industry my post alerts to enforcement agencies.
Responsibilities of the manufacturer about detection and reporting of falsified medical product are defined in the following ordinances:

1. *Ordinance on good practice in the marketing of medicinal products, granting licenses for the wholesale distribution of medicinal products, granting licenses for the intermediation of medicinal products and issuing a certificate of good practice in the wholesale distribution of medicinal products (Official Gazette 83/13)*
2. *Ordinance on the conditions and manner of determining the requirements for good manufacturing practice and good practice in wholesale of active substances and on the procedure for entry in the register of manufacturers, importers and wholesalers of active substances and issuing a certificate of good manufacturing practice (Official Gazette 83/13.)*
3. *Ordinance on the suspension of the placing on the market and withdrawal of a medicinal product (Official Gazette 122/14) and the Ordinance on the quality control of medicinal products (Official Gazette 60/14) which regulate the procedure in the event of a counterfeit medicinal product.*

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?

Market surveillance through monitoring the quality and safety of medical products in the market including falsified medicines is included in Strategic plan of Agency for Medicinal Products and Medical Devices (HALMED). According to the Medicinal Products Act (Official Gazette 76/13) Agency for medicinal products and medical devices is responsible for regular quality control according to the annual sampling plan (Article 176) and for extraordinary, unscheduled quality control in the cases of quality defects and suspected falsified medical products (article 177).

Article 176

(1) The Agency shall conduct quality control of medicinal products taken from distribution by the pharmaceutical inspection at least once in five years for each pharmaceutical form and each strength of the medicinal product.
(2) The Agency may conduct quality control of galenic preparations taken from distribution by the pharmaceutical inspection.

Article 177

(1) Unscheduled quality control shall be conducted at the request of the Ministry or the Agency in the event of any unusual signs or suspected quality defects or suspected falsified medicinal products or galenic preparations, and it shall be carried out by the Agency.

Effectiveness of this measures is assessed in yearly Activities Report (presented also to the Government) and Management Review.

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?

According to the Medicinal Products Act (Official Gazette 76/13,) regular quality control according to the annual sampling plan (Article 176) and extraordinary quality control in the cases of quality defects and suspected falsified medical products (Article 177) applies to all medical products regardless of the place of purchase.

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, if customs officers would detect suspected counterfeit medical products (as defined in Article 4.j) they would inform Pharmaceutical inspection.

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.

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?

Article 185 of the Criminal Code

Counterfeiting of Medicines or Medical Products

Article 185 of the Criminal Code

(1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years.

(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia.

(3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years.

(4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices.

The definition of medicinal product and medical devices are in the relevant
Medicinal Products Act

Article 3
For the purposes of this Act, the following terms shall bear the following meanings:
1. Medicinal product shall mean:
- any substance or combination of substances presented as having properties for curing or
preventing disease in human beings, or
- any substance or combination of substances which may be used or administered to human
beings either with a view to restoring, correcting or modifying physiological functions by
exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis,

Medical Devices Act
Article 3
For the purposes of this Act the following definitions shall apply:
1. 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

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?

Medicinal Products Act

Article 3
49. Falsified medicinal product any medicinal product which is deliberately and fraudulently mislabelled with respect to:
a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
b) its source, including its manufacturer, its country of manufacturing, its country of origin or
its marketing authorisation holder, or
c) its history, including the records and documents relating to the distribution channels used.
This definition shall not apply to unintentional quality defects and 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.

Article 185 of the Criminal Code

Counterfeiting of Medicines or Medical Products

Article 185 of the Criminal Code

(1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years.

(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia.

(3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on

the active substance or excipient shall be punished by imprisonment not exceeding three years.

(4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices.

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.
See answer C)
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.

Article 185 of the Criminal Code

Counterfeiting of Medicines or Medical Products

Article 185 of the Criminal Code

(1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years.

(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia.

(3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years.

(4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices.

(5) Whoever commits the offence referred to in paragraph 1, 2, 3 or 4 of this

Article by abusing the trust he or she enjoys as an expert, manufacturer or supplier, or commits it through the media suitable for mass distribution, such as information systems, including the internet, shall be punished by imprisonment from one and eight years.

(6) The attempt of the criminal offence referred to in paragraph 3 or 4 of this Article shall be punishable.

(7) Products and means of production shall be confiscated.

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)?

According to the Croatian internal law a legal person may be held liable for an offence established in accordance with Article 11 of the MEDICRIME Convention. In the Republic of Croatia the liability of legal persons for criminal offences is criminal liability.

The preconditions of punishability of legal persons are prescribed by the following Articles of the Act on the Responsibility of Legal Persons for Criminal Offences (Official Gazette nos 151/03, 110/07, 45/11, 143/12, hereinafter: the ARLPCO).

The Grounds for the Responsibility of Legal Persons

Article 3 of the ARLPCO

(1) A legal person shall be punished for a criminal offence committed by the responsible person if thereby a duty of that legal person is violated or if the legal person thereby obtained or should have obtained unlawful pecuniary advantage for itself or another.

(2) Under the conditions referred to in paragraph 1 of this Article, a legal person shall be punished for criminal offences prescribed by the Criminal Code and other laws in which criminal offences are prescribed.

The Responsible Person

Article 4 of the ARLPCO

The responsible person within the meaning of this Act is the natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided

Assignment of Guilt of the Responsible Person to the Legal Person

Article 5 of the ARLPCO

(1) The responsibility of the legal person is based on the guilt of the responsible person.

(2) The legal person shall be punished for a criminal offence committed by the responsible person even if the existence is established of legal or material hindrances for establishing the responsibility of the responsible person.

The liability of the legal person is without prejudice to the criminal liability of the natural person who have committed the offence, and this is conclusive from Article 5 paragraph 2 of the ARLPCO, as well as from the Article 23 of the ARLPCO, which reads:

Joined procedure

Article 23 of the ARLPCO

(1) For a criminal offence committed by the legal person and the responsible person, joined proceedings shall be conducted and a single judgement shall be passed.

(2) If no criminal proceedings may be instituted or conducted against the responsible person for legal or any other reasons whatsoever, the proceedings shall be instituted and conducted against the legal person only.

Under the ARLPCO the basis of criminal responsibility of legal person is a criminal offence comitted by responsible person of legal person. Responsibility of legal person is based on the guilt of the responsible person (Article 5 of the ARLPCO).
Responsible person within the meaning of the ARLPCO is a natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided (Article 4 of the ARLPCO).
In accordance with the prescribed legal definition, responsible person is not only a natural person in a leading position who conducts the affairs of legal person (e.g. member of supervisory board), but also a natural person who is under the authority of a person in a leading position, to whom running of affairs from the sphere of activity of legal person has been confided. This is the so-called extended /delegation (derived) model of liability of legal persons in which the liability of a legal person is based on the actions of not only members of the management and supervisory board but also persons ranked lower in the decision-making hierarchy, provided that they are entrusted with conducting the affairs from the scope of operation of legal person.
The basis of criminal responsibility of legal person is the fact that a responsible person violated any of the duties of the legal person or the fact that the legal person obtained or should have obtained unlawful pecuniary advantage for itself or third person by criminal offence committed by a responsible person (Article 3 of the ARLPCO).
Article 11 paragraph 2 of the MEDICIRME Convention prescribes the criminal liability of legal person where the lack of supervision or control by any natural person, acting either individually or as part of an organ of the legal person, and having a leading position within the legal person, has made possible the commission of an offence established in accordance with the MEDICIRME Convention for the benefit of that legal person by a natural person acting under its authority.
Subsequently, based on Article 3 in the acquisition with Article 4 and 5 of the ARLPCO if a natural person under the authority of a natural person in leading position, commits intentionally

criminal offence for the benefit of the legal person, as a consequence of lack of supervision or control of a natural person in leading position, the liability of legal person will be based on the guilt of a natural person who is not a person in leading position, but has the capacity of responsible person under Article 4 of the ARLPCO and the guilt of the natural person in leading position which had made possible the commission of the criminal offence by the lack of supervision or control. Thus, the model of liability of legal persons for criminal offenses in Croatian legislation, according to which criminal offence may be committed by acting or by omitting to act, is fully in line with the requirements of Article 11 of the MEDICRIME Convention.

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

In Criminal Police Department of Ministry of Internal Affairs there are specialised units like Organised Crime Department, Cyber Crime Department of Ministry of Internal Affairs, International Police Co-operation Department that are dedicated for investigation in the field of falsified medical products. :

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

Lead roles lie within the Ministry of Internal Affairs or Customs Administration of the Ministry of Finance. Both the Ministry of Internal Affairs and Customs act as enforcement bodies, whilst HALMED gives support in gathering information on counterfeits, cooperates in analysis and quality control of suspected products and shares information on medical products.

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

There are no specialized prosecutors and they function on a national and on a 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.

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;

Within the police there are specialised cybercrime units with the extended competence to investigate counterfeit medicine. There is a unit on the national level responsible for the EU

and international cooperation and regional units responsible for the cases reported to them or for the cases that occurred within their jurisdiction.

Law on Police Affairs and Powers *and*

Rulebook on the manner of conduct of police officers

V. CRIMINAL INVESTIGATION

Article 38

Criminal investigation begins with the opening of analytical processing or the beginning of the investigation of a criminal offense for which he is prosecuted ex officio or on the basis of a proposal or misdemeanor or by an urgent evidentiary action of a criminal offense or misdemeanor.

Criminal investigation generally understands: analytical processing, investigations of a criminal offense or misdemeanor, and final action.

The beginning of the investigation of criminal offenses that are prosecuted ex officio and upon the proposal is approved by the competent manager at the proposal of the Task Force and Coordination Group.

The criminal investigation is led by a certain police officer. The police officer, on the order of the competent manager, compiles the Criminal Investigation Plan. The criminal investigation plan is approved by the competent manager.

Started criminal investigations are entered in the Collection of Criminal Investigations, which is kept on the Information System of the Ministry.

The criminal investigation ends:

- closing analytical processing;

- if the conducted investigations determine that it is not a criminal offense for which he is prosecuted ex officio or a misdemeanor;

- by filing a criminal report or a special report against the perpetrator of a criminal offense or by initiating misdemeanor proceedings.

Exceptionally, if there is no data necessary for the completion of the criminal investigation at the written proposal of the police officer who conducted the criminal investigation, the superior may grant a temporary suspension of the criminal investigation if all necessary measures and actions have been taken and all available data checked.

Reactivation of the criminal investigation referred to in paragraph 7 of this Article in the case of new findings shall be approved by the superior manager at the proposal of the Task Force and Coordination Group.

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 are no different processes related to the 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.

Based on the legislation provisions, healthcare professionals, marketing authorisation holders and all natural and legal persons involved in manufacturing and distribution of medicinal products and active substances are obliged to inform the Agency for Medicinal Products and Medical Devices (HALMED) on any suspicion of a quality defects or a suspicion of a counterfeit medicinal product. Patients/users may also report to the Agency a suspicion of a quality defect or a counterfeit medicinal product.
Agency may also receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior.

The legislation defines the responsibilities and timelines for handling such reports and information received, as well as the responsibilities of the Agency to exchange the information as defined in the Compilation of Community Procedures on Inspections and Exchange of Information.

Agency is responsible for evaluation and processing of each received report/information on suspected quality defect and counterfeited/falsified medicinal product. Records are kept within the Agency's databases and archive.

In order to report any suspicion of a quality defect, adverse drug reaction or counterfeit medicinal product, contact numbers and email addresses for Rapid alert system are available on the Agency's website :

Telephone: +385 800 48 00 08 (24 hours a day, free of charge, only for rapid alerts that could lead to a recall)
Mobile phone: +385 99 264 6417 (24 hours a day, for rapid alerts that could lead to a recall)
Telephone: +385 1 4884 100 (switchboard)
Telefax: +385 1 4884 120 (for rapid alerts that could lead to a recall)
E-mail: neispravnost@halmed.hr (for all quality defects)
Email: nuspojave@halmed.hr (for adverse drug reactions)
Email: krivotvorine@halmed.hr (for suspicion in a counterfeited/falsified medicinal products)

Handling of quality defects, suspicions in counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit

Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was found to be in compliant with the defined legal requirements and set procedures.

Legislation provisions:

Medicinal Products Act (Official Gazette No. 76/13, 90/14 and 100/18)

Article 62
(1) The Agency shall suspend the market placement of the medicinal product and request its withdrawal from the market in one of the following cases:
- the medicinal product is unacceptably harmful, or
- the therapeutic effect of the medicinal product is insufficient, or
- the risk-benefit balance is unfavourable, or
- the qualitative and/or quantitative composition of the medicinal product is not as declared, or
- the quality and composition or the medicinal product and intermediate product have not been subjected to control, or
- the medicinal product is not manufactured in accordance with the manufacturing licence, or
- the medicinal product is falsified.

Article 181
(1) Healthcare professionals who come in contact with a medicinal product or with a user of the medicinal product, as well as legal and natural persons who manufacture or distribute medicinal products, shall inform the Agency in writing of any incompliance in the quality of the medicinal product brought to their attention.
(2) In the event of suspected falsified medicinal products, the persons from paragraph 1 of this Article shall notify the Agency of their suspicion within 24 hours.
(3) The ordinance on the method for monitoring incompliances in the quality of medicinal products and the ordinance on falsified medicinal products shall be issued by the Minister.

Ordinance on the Suspension of the Placement on and Withdrawal of Medicinal Products from the Market (Official Gazette No. 122/14):

Article 2
1) Health care professionals coming into contact with medicinal products, or patients/users of medicinal products and legal and natural persons producing or performing the trade of medicinal products are obliged, in the cases that could be the reason for the suspension of the placement on and withdrawal of medicinal products from the market from Article 62 of the Medicinal Products Act (hereinafter: the Act), are obliged to notify the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) thereof in writing.
2) The patient/user of the medicinal product may report a suspicion of an irregularity in the quality of the medicinal product, or suspicion of a counterfeit medicinal product, to the Agency.
3) In addition to persons from paragraphs 1 and 2 of this Article, the Agency may receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior.
Article 6

1) The holder of the marketing authorisation for the medicinal product, holder of the authorisation for the parallel import of the medicinal product, manufacturer of the medicinal product, importers and wholesalers included in manufacturing or in performing wholesale trade of medicinal products are obliged to inform the Agency in writing of each observed case from Article 2 of this Ordinance which could result in the suspension of the placement on or withdrawal of the medicinal product from the market, or limitations to the use of the medicinal product that are not listed in the approved summary of product characteristics and the approved package leaflet.
2) In the case of a suspicion of an irregularity in the quality of a medicinal product, the natural and legal persons from paragraph 1 of this Article are obliged to inform the Agency in writing within:
– 12 hours of determining the irregularity, if the irregularity corresponds to a Class I irregularity from Article 12 of this Ordinance,
– 24 hours of determining the irregularity, if the irregularity corresponds to a Class II irregularity from Article 12 of this Ordinance, or for a suspicion of a counterfeit medicinal product,
– 7 days of determining the irregularity, if the irregularity corresponds to a Class III irregularity from Article 12 of this Ordinance.

….

Article 8
1) The Agency shall process every received report from Articles 3, 5 and 6 of this Ordinance immediately upon receipt.
2) The Agency shall determine the responsible person for cases that may be reason for the suspension of placement on or withdrawal of a medicinal product from the market and who will be available 24 hours a day.
….

Article 13
1) In the case of a received report of a suspicion of a counterfeit medicinal product, the Agency shall request the pharmaceutical inspection conduct sampling of the medicinal product in order to perform special quality tests and if necessary to implement the procedure prescribed by Article 11, paragraph 1, subparagraph 2 and 3 of this Ordinance.
2) If the suspicion of counterfeiting is confirmed, the Agency shall, via the Notification Centre of the Republic of Croatia, inform the users of the withdrawal of the medicinal product from the market, while if the legal participant in the marketing of the medicinal product is not determined, the withdrawal procedure shall be carried out by the pharmaceutical inspection.

….

Ordinance on the conditions for issuing manufacturing authorisations, on the requirements of good manufacturing practice and on the certificate of good manufacturing practice for medicinal products (Official Gazette No. 83/13 and 32/21):
Article 19
…
(2) Any complaint concerning a defect shall be recorded and investigated by the manufacturer and the importer of the medicinal product.
…

Article 20
…
(2) The manufacturer or the importer of a medicinal product shall record and investigate any complaint concerning a defect referred to in paragraph 1 of this Article and shall inform the Ministry and the Agency of any defect that could result in a recall or abnormal restriction on use of the medicinal product.
…

Ordinance on the Requirements and Method of Establishing the Requirements of Good Manufacturing Practice and Good Practice in the Wholesale of Active Substances and on the Procedure of the Entry in the Register of Manufacturers, Importers and Wholesalers of Active Substances, and on Issuing the Certificate for the Implementation of Good Manufacturing Practice (Official Gazette No. 83/13 and 32/21):
Article 20
The holder of the entry in the register of manufacturers, importers, or wholesalers shall, immediately and in writing, notify the Agency if he finds out that the active substance received or offered to them is counterfeit or suspected as counterfeit.

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?

Based on the legislation provisions, healthcare professionals, marketing authorisation holders and all natural and legal persons involved in manufacturing and distribution of medicinal products and active substances are obliged to inform the Agency for Medicinal Products and Medical Devices (HALMED) on any suspicion of a quality defects or a suspicion of a counterfeit medicinal product. Patients/users may also report to the Agency a suspicion of a quality defect or a counterfeit medicinal product.
Agency may also receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior.

The legislation defines the responsibilities and timelines for handling such reports and information received, as well as the responsibilities of the Agency to exchange the information as defined in the Compilation of Community Procedures on Inspections and Exchange of Information.

Agency is responsible for evaluation and processing of each received report/information on suspected quality defect and counterfeited/falsified medicinal product. Records are kept within the Agency's databases and archive.

Handling of quality defects, suspicions in counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit

Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was found to be in compliant with the defined legal requirements and set procedures.

Legislation provisions:

Ordinance on the Suspension of the Placement on and Withdrawal of Medicinal Products from the Market (Official Gazette No. 122/14):
Article 8
1) The Agency shall process every received report from Articles 3, 5 and 6 of this Ordinance immediately upon receipt.
2) The Agency shall determine the responsible person for cases that may be reason for the suspension of placement on or withdrawal of a medicinal product from the market and who will be available 24 hours a day.
….

Please refer to the answer to the Question 30 for more details.

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 prescribed offences are investigated. Offences established in accordance with this Convention are no subordinate to a complaint and proceedings may continue even if the complaint is withdrawn.

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)?

There is a possibility for competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

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?

In all cases, according to the Criminal Procedure law, investigating bodies must notify prosecuting authority that criminal investigation has begun. After completing criminal investigation, investigating bodies also have to notify prosecuting authority of the outcome of the criminal investigation.

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).

Article 185 of the Criminal Code

.

…

(7) Products and means of production shall be confiscated.

Aiding and abetting the commission of criminal offences established in accordance with the MEDICIRME Convention shall be punished on the basis of general institutes prescribed by Articles 37 and 38 of the Criminal Code. These provisions are located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, they apply to all criminal offences prescribed by the Criminal Code.

Confiscation of Objects

Article 79 of the Criminal Code

(1) The objects and means which are the products of criminal offence shall be confiscated.

(2) The court may confiscate objects and means which were intended to be used or were used in the commission of a criminal offence.

(3) The court may confiscate objects and means referred to in paragraph 1 and 2 of this Article also in cases where the perpetrator of the unlawful act is not guilty.

(4) The confiscated objects and means shall become the property of the Republic of Croatia. This does not affect the rights of third parties to claim damages against the perpetrator for the confiscation of an object or a means. Unless at least his/her gross negligence has contributed to the object or means being intended to be used or being used in the commission of a criminal offence or to its being the product of commission of a criminal offence or if he/she procured the object or means knowing about the conditions allowing for its confiscation, the owner of the confiscated object or means who is not the perpetrator of the offence is entitled to the return of the object or means or to damages equal to its market value paid from the state budget.

(5) Unless otherwise provided for in a special act, the law may prescribe mandatory confiscation of an object or means, in which case the owner shall not be entitled to damages paid from the state budget.

(6) The court may order the destruction of the confiscated object or means.

The pecuniary advantage acquired from the commission of the criminal offence referred to in Article 185 of the Criminal Code shall be confiscated on the basis of Article 5 and 77 of the Criminal Code, which apply to all criminal offences prescribed by the Criminal Code.

Principle of Confiscation of the Pecuniary advantage

Article 5 of the Criminal Code
No one shall retain the pecuniary advantage acquired from an unlawful act.

Conditions for and Manner of Confiscation of Pecuniary Advantage

Article 77

(1) Pecuniary advantage shall be confiscated on the basis of a court decision establishing the commission of an unlawful act. Pecuniary advantage shall also be confiscated from the person to whom it was transferred if it was not acquired in good faith.

(2) If the injured party has been awarded a material claim which by its nature and contents corresponds to the acquired pecuniary advantage, the part of pecuniary advantage exceeding the awarded material claim shall be confiscated.

(3) The court shall confiscate the pecuniary advantage also in cases where it has instructed the injured party to assert his or her material claim in a civil action.

(4) Where it has been established that confiscation in full or in part of objects or rights acquired as pecuniary advantage is impossible, the court shall order the perpetrator to pay the corresponding money equivalent. It may be ordered that payment be made in instalments.

(5) The confiscated pecuniary advantage shall not be reduced by the value of resources invested in the criminal activity.

(6) The court may decide against the confiscation of pecuniary advantage if its value is negligible.

In case the criminal offence referred to in Article 185 of the Criminal Code is committed within the framework of the criminal organization, the Article 78 of the Criminal Code shall also apply.

Extended Confiscation of Pecuniary Advantage

Article 78

(1) Unless otherwise prescribed by this Article, the provisions of Article 77 of this Code shall apply to the extended confiscation of pecuniary advantage acquired by criminal offence for which the Office for the Suppression of Corruption and Organised Crime is competent and by criminal offences prescribed by Titles XVII. an XXV. of this Code, if pecuniary advantage was acquired by those criminal offences.

(2) If the perpetrator of a criminal offence referred to in paragraph 1 of this Article posseses or possesed property that is disproportionate with his or her legitimate income and unless he or she makes it probable that the property is of legitimate origin, it is presumed that such property constitutes a pecuniary advantage.

(3) If the pecuniary advantage from a criminal offence have been merged into legitimately acquired property, the entire property shall be subject to confiscation up to the estimated value of the pecuniary advantage. The advantage acquired from property in which the legitimately acquired property was merged with the pecuniary advantage shall also be confiscated in the same manner and in the same ratio.

(4) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall be confiscated from a family member irrespective of the legal basis on which he or she possesses it and regardless of whether he or she lives in a shared household with the perpetrator.

(5) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall also be confiscated from another person irrespective of the legal basis on which it was acquired unless this person makes it probable that he or she acquired the advantage in good faith and at a reasonable price.

(6) If the person against whom criminal proceedings have been instituted dies, the pecuniary advantage acquired by an unlawful act may be confiscated from his or her successors in proceedings prescribed by a special act.

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?

Counterfeiting of Medicines or Medical Products

Article 185 of the Criminal Code

(1) Whoever manufactures a counterfeit medical, active substance, excipient, medical product, its components or paraphernalia, or modifies a genuine medicine, active substance, excipient or medical product, its components or paraphernalia shall be punished by imprisonment for from six months to five years.

(2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified a medicine, active substance, excipient, medical product, its components or paraphernalia.

(3) Whoever counterfeits or modifies the original inner or outer package of a medicine or medical product, summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years.

(4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicine or medical product, the summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicines and medical products.

(5) Whoever commits the offence referred to in paragraph 1, 2, 3 or 4 of this Article by abusing the trust he or she enjoys as an expert, manufacturer or supplier, or commits it through the media suitable for mass distribution, such as information systems, including the internet, shall be punished by imprisonment from one and eight years.

(6) The attempt of the criminal offence referred to in paragraph 3 or 4 of this Article shall be punishable.

(7) Products and means of production shall be confiscated.

Aiding and abetting the commission of criminal offences established in accordance with the MEDICIRME Convention shall be punished on the basis of general institutes prescribed by Articles 37 and 38 of the Criminal Code. These provisions are located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, they apply to all criminal offences prescribed by the Criminal Code.

Solicitation

Article 37 of the Criminal Code

(1) Whoever intentionally incites another to commit a criminal offence shall be punished as if he or she himself or herself has committed it.

(2) Whoever intentionally incites another to commit a criminal offence for which an attempt is punishable, but the solicited offence has never even been attempted, shall incur the penalty provided for an attempt to commit such an offence.

(3) In the case of an inappropriate attempt of solicitation, the solicitor may receive remittance of punishment.

Aiding and Abetting

Article 38 of the Criminal Code

Punishment may be equal or mitigated to whoever intentionally aids and abets another in the commission of a criminal offence.
The attempt to commit criminal offences established in the accordance with the MEDICIRIME Convention shall be punished, as follows:

The attempt to commit criminal offences referred to in Article 185 paragraphs 1, 2 and 5 of the Criminal Code is punishable according to Article 34 of the Criminal Code. This provision prescribes the conditions for the attempt to commit a criminal offence to be punishable and it is located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, it applies to all criminal offences prescribed by the Criminal Code.

Attempt

Article 34 of the Criminal Code

(1) Whoever, with the intent to commit a criminal offence, performs an act which is spatially and temporally proximate to the realisation of the material elements of the criminal offence shall be punished for the attempt, provided that a sentence of imprisonment of five years or a more severe punishment may be imposed or that the law expressly provides for the punishment of an attempt.

(2) The punishment of a perpetrator of an attempt may be mitigated.

(3) If the perpetrator due to gross ignorance attempts to commit a criminal offence by unsuitable means or towards an unsuitable object the court may remit the punishment.

The attempt to commit criminal offences referred to in Article 185 paragraphs 3 and 4 of the Criminal Code (for which the maximum sentence prescribed is three years of imprisonment) is punishable on the basis of Article 185 paragraph 6 of the Criminal Code.

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?

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?

Circumstances referred to in Article 13 paragraphs b), c) and d) of the MEDICRIME Convention are constituent elements of the qualified form of the criminal offence Counterfeiting of Medicines or Medical Products referred to in Article 185 paragraph 5 of the Criminal Code.

Circumstances referred to in Article 13 paragraphs a), e) and f) of the MEDICRIME Convention may be taken into consideration in the determination of sentence according to Article 47 paragraph 1 of the Criminal Code. This provision is located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, it applies to all criminal offences prescribed by the Criminal Code.

Determination of Punishment

Article 47 of the Criminal Code

(1) When determining the type and range of punishment, the court shall, starting from the degree of culpability and the purpose of punishment, assess all the circumstances affecting the severity of punishment by type and range (mitigating and aggravating circumstances), and especially the degree of threat to or violation of a legally protected good, motives for having committed the criminal offence, degree to which the perpetrator's duties have been violated, manner of commission and the inculpatory consequences arising from the commission of the criminal offence, perpetrator's prior life, his or her personal and pecuniary circumstances and his or her conduct following the commission of the criminal offence, relationship to the victim and efforts to compensate for the damage.

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).

Act on Medicine

Termination of the right to practice medicine
Article 7

The right of a doctor to perform medical activity ceases:

1. if he loses Croatian citizenship,
2. if he loses his legal capacity,
3. if he becomes permanently unhealthy to perform medical activities,
4. if a security measure of prohibition of performance has been imposed on him medical activities,
5. if the disciplinary sanction of the body of the Croatian Medical Chamber lost the right to practice medicine.

Unworthiness to perform medical activity

Article 8

A doctor who has been found guilty by a final court decision for the commission of a criminal offense may, given the importance of the nature of the endangered good or other consequences and with regard to the circumstances under which the action was performed or missed, considered unfit to practice medicine.

The doctor referred to in paragraph 1 of this Article may be denied administration approvals for independent work, ie temporarily or permanently revoked approval for independent work.

Depending on the type of crime and the consequence it had, the doctor referred to in paragraph 1 of this Article may be temporary or permanent limited authorization for independent work given the scope and the type of work that the doctor is allowed to do.

Unworthiness to perform medical activity is determined by an administrative act, a body determined by the Statute of the Croatian Medical Association chambers.

Act on Pharmacy

Article 29

The Chamber may temporarily or permanently revoke the master's degree in pharmacy from independent work.

The approval is temporarily revoked for a period of up to one year, ie for the reasons for which the approval was revoked.

Approval shall be suspended:

- if the master of pharmacy has not fulfilled the conditions prescribed by the general act of the Chamber of Professional Development for the purpose of maintaining and improving the quality of health care, for the period until he meets the required conditions,

- if the Master of Pharmacy is temporarily prohibited from performing pharmacy activity by a decision of the Chamber of the Chamber, a final decision of a regular court or a decision of another body,

- if the master of pharmacy in his work acts contrary to the provisions of this Act, for a period until he eliminates such action.

Approval is revoked permanently:

- if the master of pharmacy is permanently prohibited by the decision of the court of the Chamber, a final court decision or a decision of another body from performing pharmacy activity.

Medicinal Products Act

Article 80
(1) The Agency shall, ex officio, issue a decision on cancellation of the manufacturing authorisation if it is established that the manufacturer does not comply with the requirements laid down by this Act and the ensuing regulations.
(2) On the basis of a written application of the authorisation holder the Agency shall by a decision revoke the manufacturing authorisation if the authorisation holder ceases its activity.
(3) The decision on revoking or withdrawing of the manufacturing authorisation cannot be appealed, but administrative proceedings can be instituted against it.

ORDINANCE ON THE REQUIREMENTS AND METHOD OF ESTABLISHING THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICE AND GOOD PRACTICE IN THE WHOLESALE OF ACTIVE SUBSTANCES AND ON THE PROCEDURE OF THE ENTRY IN THE REGISTER OF MANUFACTURERS, IMPORTERS AND WHOLESALERS OF ACTIVE SUBSTANCES, AND ON ISSUING THE CERTIFICATE FOR THE IMPLEMENTATION OF GOOD MANUFACTURING PRACTICE

VIII. DELETION FROM THE REGISTER
Article 35
The Agency shall issue a decision on the deletion of manufacturers, importers, or wholesalers of active substances from the Register in the following cases:
– at the request of the holder of the entry in the Register,
– if the holder of the entry in the Register is not registered in the court register, or crafts register,
– if it has been established after an inspectional supervision that the holder of the entry in the Register does not meet the requirements for the implementation of activities of manufacturing active substances pursuant to the Act and this Ordinance.

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.
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.

Data about tested falsified medical products are stored in database of Agency for medicinal products and medical devices. This data are shared with the OMCL network and with other authorities through Rapid Alert System and the KnowX database. Data about falsified medical products found during police and customs investigation and not tested also are shared through Know X database and Rapid Alert System.

Agency for medicinal products and medical devices yearly is obliged to prepare a report on its activities related to falsified medical products for the OMCL network.

In the framework of CD-P-PG/CMED working group (EDQM, Council of Europe) there is also a form of exchange of information about falsified medicinal products and medical devices especially during pandemic.