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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

Switzerland's reply of 25 November 2021

Introduction

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

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

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

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

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

5. It is recalled that, in accordance with Rule 26 of the Committee's Rules of Procedure:

> *"(…) 2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*

[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.

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)?

Answer 1a:

Swissmedic (Swiss Agency for Therapeutic Products) provides a variety of targeted information, primarily on the website www.swissmedic.ch (factsheets for wholesalers, etc.). Furthermore, presentations are given to targeted groups, e.g. healthcare professionals (answer b) or law enforcement officials, or round tables are held with stakeholders or dialogues held with the industry).

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

Answer 1b:

The Federal Customs Administration (FCA) has jurisdiction for the enforcement of national intellectual property legislation (trademark law, patent law, design law, indications of source, copyright law) as well as the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). Therefore, adequate training is provided to customs officers for the execution of tasks.

Moreover, in the field of combating the import, export and transit of counterfeit medicines, the FCA works closely with Swissmedic, which acts as the single national contact point (SPOC). Swissmedic provides scientific and technical support to the FCA in the execution of its tasks.

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

Answer 1c:

Close cooperation is ensured between Swissmedic and customs authorities to conduct targeted market surveillance campaigns (including training), and regular training of customs officers is carried out by Swissmedic. During the current pandemic, market surveillance operations were conducted by FCA and Swissmedic. These operations (Op. STOP I and STOP II, including training) were conducted under the umbrella of the World Customs Organization and were targeted against illegal medical products used for prevention and treatment of COVID-19.
Furthermore, prosecution under penal law for violations of legislation on therapeutic products is one of Swissmedic's core processes (in addition to licensing, authorisation and market surveillance). While having these competences, the Penal Division of Swissmedic has the possibility of rapidly and easily accessing its scientific units if need be, thus enhancing the efficacy and efficiency of its procedures, particularly in complex and/or international cases.
The various responsibilities in law enforcement under the Therapeutic Products Act (TPA) and the provision of smooth, efficient and effective law enforcement require a good, immediate flow of information and optimised cooperation between all actors. There is close cooperation between the Penal Division of Swissmedic and the Cantonal and Federal Prosecutor's Offices and law enforcement agencies. Swissmedic is responsible for monitoring the uniform correct application of the TPA and provides expertise on the topic to prosecutors and police officers through thematic information sharing, presentations and training.

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)?

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?

Answer 3:

Swissmedic provides a variety of targeted information, primarily on its website www.swissmedic.ch (factsheets, etc.). Furthermore, with regard to waste disposal during the current pandemic, vaccination centres and the responsible supervising authorities were made aware of the Advice on the application of the Medicrime Convention in the context of

counterfeit COVID-19 vaccines, with a focus on correct waste management of empty vaccine vials.

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;

Answer 6a:

Swissmedic provides a variety of targeted information (factsheets, etc.), primarily on its website (www.swissmedic.ch). Regarding the current pandemic, Swissmedic has issued specific warnings:

- against purchasing non-conforming and illegal medical devices,
- against purchasing illegal medicinal products which are used against COVID-19, and
- against purchasing COVID-19 vaccines on a private basis.

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.

Answer 6b and 6c:

Swissmedic regularly conducts public awareness campaigns (e.g. annual Operation PANGEA, and awareness campaigns within the framework of the Swiss public-private partnership STOP PIRACY), and issues regular publications regarding the health risks of purchasing drugs from illegal sources and ad hoc publications regarding specific dangerous illegal medicines.

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

Answer:
No, there are no reports.

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.

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.

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)?

Answers 9:

Swissmedic is the central contact point for reports regarding illegal advertisement and illegal offers and takes measures against any such activities contrary to national laws. Together with the national communications authority, Swissmedic has assessed all new websites that included "COVID", "corona" or similar words in their domain name in order to uncover illegal

offers or activities. Furthermore, Swissmedic conducts specific targeted monitoring of illegal virtual information and offers. In order to optimise such monitoring, tools for automated monitoring of illegal medicinal products and non-conforming medical devices are currently being evaluated.

With regard to criminal law, unlawful advertising is punishable under the TPA (Article 87, para. 1, letter (b) in connection with Article 32). Pursuant to Article 32, para. 1 TPA, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (letter (a)), if it may incite an excessive, abusive or inappropriate use of medicinal products (letter (b)) or if it is for medicinal products which may not be placed on the market nationally or cantonally (letter (c)). Fines of up to CHF 50,000.00 may be imposed in case of a violation of this provision (cf. Article 87, para. 1).

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)?

Answer 10:

Persons injured by counterfeit medical products have the status of victims within the meaning of the CrimPC and the VSA if their physical or psychological integrity has been directly affected. Victims within the meaning of the CrimPC can participate in criminal proceedings, whereas under the VSA, victims enjoy certain benefits such as advice and assistance, compensation and satisfaction.

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)?

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).

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.

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).

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).

Answer 15:

Within the national network of authorities engaged in enforcement against counterfeit medical products and similar crimes, a scheme on cooperation and information exchange has been adopted at their annual Medicrime Meeting. This scheme is promoted, reviewed and adapted annually by the national network.

This scheme is valid for non-pandemic and pandemic situations.

Additionally, Fedpol has established a distribution list for all information related to COVID-19 that comes through police networks. The national contact point according to Article 22.2 is included in this distribution list.

So far, Switzerland, i.e. the authorities with regard to market supervision of therapeutic products, have not adopted any specific measures for pandemic situations. Swissmedic, Swiss Agency for Therapeutic Products, is currently working on an enforcement-strategy for the new strategic period (2023-2026).

Question 16. **(optional)**

a. Is the implementation of such national strategy and/or action plan supported and underpinned by enabling legislation for the transfer and receipt of information and data between authorities/bodies and to and from other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2)?
b. Are there specific Memorandum of Understanding (MOU) and/or Data Sharing Agreements (DSA) between bodies, at national and international levels, to give effect to arrangements between authorities/bodies in combating counterfeit medical products and similar crimes. Have they been adopted specifically because of the COVID-19 pandemic?
c. Please describe briefly, and without going into detail, the practical measures that ensure the implementation and effectiveness of the MOUs and DSAs, including periodic reviews.

Question 17. **(optional)**

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

Question 18. **(optional)**

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

Question 19. (optional)

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

Question 20. (optional)

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

Question 21. (optional)

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

Question 22. (mandatory)

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

Answer 22:

In accordance with the Convention and following the entry into force of the revised TPA on 1 January 2019, Swissmedic became the national SPOC according to Art. 69, para. 4 of the new legislation.
There is close cooperation between this national SPOC division and the Swissmedic Penal Division, which is responsible for prosecuting and penalising violations relating to the manufacture, supply and trafficking of illegal therapeutic products. Violations in connection with the use and dispensing of therapeutic products fall under the competence of the cantonal prosecution authorities. Swissmedic's Penal Division, the Office of the Attorney General (OAG) and the cantonal prosecuting authorities have a very close, active and efficient exchange of information, thus ensuring uniform prosecution of violations relating to the TPA throughout Switzerland (cf. answer 1).
The exchange of confidential data between the (federal and cantonal) enforcement authorities in Switzerland and between the federal enforcement authorities and foreign authorities/institutions is enabled by law, cf. Art. 63 and 64 TPA.

With regard to criminal proceedings, the cantonal prosecution authorities have an obligation to inform Swissmedic of the initiation of preliminary proceedings relating to the TPA (Article

90, para. 3 TPA). Furthermore the Penal Division of Swissmedic may exercise the rights of a private claimant in the proceedings. Additionally, the Ordinance on the Notification of Cantonal Criminal Decisions requires the cantonal prosecution authorities to inform (i.e. supply with a copy) Swissmedic about their criminal decisions based (also or solely) upon the TPA (cf. Article 3 No. 15).
In the international context, Switzerland ratified the European Convention on Mutual Assistance in Criminal Matters (entry into force 20 March 1967). The prosecutor's offices in Switzerland fulfil mutual legal assistance in close cooperation with the Federal Office of Justice, based on the Federal Act on International Mutual Assistance in Criminal Matters (Mutual Assistance Act, IMAC). On the police level, the Federal Office of Police (fedpol) is the central agency for police co-operation. The office helps to build and maintain contacts between the cantonal police and law enforcement agencies, and between them and international partners. Within fedpol, the Directorate for International Police Co-operation, with its Operations Centre, and the Directorate of Federal Criminal Police are primarily entrusted with various aspects of international co-operation. The latter is part of the "coordination group Medicrime", which regularly holds meetings with Swissmedic and the Federal Customs Administration.

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?

Answer 23:

Reporting of suspected trafficking and counterfeiting in medicinal products has been introduced in the Therapeutic Products Act as a mandatory requirement for industry with the ratification of the Medicrime Convention. A specific form and information sheet are provided on the Swissmedic and Medicrime websites, and procedures are in place for such reporting.
The medical devices industry reports suspicions without legal obligation directly to the central Medical Devices Surveillance contact point.

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?

Answer 24:

For medical devices, a legal basis for establishing annual market surveillance plans for regional authorities with central reporting has been introduced. Because of the focus on ad hoc measures against cases of non-conforming medical devices during the pandemic, a prospective sampling programme had to be postponed.

There is no market sampling programme for detecting counterfeit medicinal products. As no counterfeit medicinal products in Swiss packaging have ever been observed, such sampling of Swiss medicinal products is not deemed necessary.

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?

Answer 25:

Answer included in Question 24. (There are no current sampling programmes, but these will be introduced for medical devices programmes; no details are available as yet).

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?

Answer 26:

Based on national intellectual property legislation, the FCA is – if requested by the rights holder - authorised to intercept counterfeits and to inform the rights holder of the intellectual property if there is any suspicion of the imminent transport of goods that unlawfully bear an intellectual property right.

In addition, if no request to protect an intellectual property right is made, based on the Therapeutic Products Act, the FCA is entrusted with the enforcement of this Act. The FCA may, within its jurisdiction and in close collaboration with Swissmedic, take all administrative measures necessary to enforce this Act. In particular, the FCA may hold back or seize therapeutic products which endanger health or which do not comply with the regulations of this Act for the initiation of further measures by Swissmedic.

Moreover, if the import, transit and export of therapeutic products also involves a violation of the Customs Act or the Value Added Tax Act, the FCA shall prosecute and judge the offences.

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 correspond to the definition in Article 4.a, even if the term is not specifically defined?

Answer 27 a:

Article 2, para. 1, letter (a) TPA contains a definition of the term 'medical product' which fully corresponds with Article 4.a of the Convention.

b. To what extent does the notion of 'counterfeiting' in internal law fully correspond 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?

Answer 27 b:

There is no legal definition of the terms 'counterfeiting' or 'counterfeit' in the TPA. However, it can be derived from Article 86, para. 1, letter (g) that the understanding of these terms under the TPA corresponds to that set out in Art. 4.j of the Convention. Pursuant to Article 86, para. 1, letter (g) TPA, any person is punishable by law, if he/she "unlawfully copies, falsifies or incorrectly names medicinal products or medical devices [i.e. medical products], or places on the market, uses, imports or exports, or trades in a foreign country, unlawfully copied, falsified

or incorrectly named medicinal products or medical devices". Therefore, there was/is no need to supplement the TPA accordingly.

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.

Answer 27 c:

Cf. the answer given above (Article 86, para. 1, letter (g) TPA).

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.

Answer 27.d:

Article 8 of the Convention concerns criminal offences in the form of intentional violations of national authorisation and compliance systems that endanger public health without referring to counterfeiting. Given that Article 8 does not require the parties to change their systems of approval and compliance and that it does not contain any additional element compared to Swiss law, the latter did not require any adaptation. The activities mentioned in Article 8 were illegal under Swiss law before the adoption of the Convention, cf. Article 86, para. 1, letter (a) and (d) TPA (formerly Article 86, para. 1, letter (b) and (e) TPA).

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.

Answer 27 e:

The falsification of attestations or certificates issued by an authority or a conformity assessment body is covered by Article 28 TBTA, to which Article 88 TPA refers. Pursuant to the TPA, the manufacture of therapeutic products is not limited to the production and composition of the chemical, biological, mechanical or electronic components serving as a basis, but also includes packaging, cf. Article 4, para. 1, letter (c). Therefore, counterfeiting of packaging, markings or package leaflets is punishable as unlawful manufacturing (Article 86, para. 1, letter (g) TPA).

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)?

Answer 27 f:

In administrative procedures in case of illegal manufacture and/or supply of medical products, it is regularly underlined that in the case of a further breach of the TPA, a penal procedure will follow.
Moreover, Swissmedic mentions in media releases, in regular newsletters to media professionals (listing penalties which entered into force) and in specific answers to the media that infringements of the TPA may be punishable.

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

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

a. any national specialised investigation units dedicated to:
    1) conducting criminal investigations, and/or
    2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure;

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

Answer 28a and 28b:

Investigations relating to counterfeit medical products are conducted on a national level by Swissmedic, the FCA and fedpol, whereas on a local level, the cantonal prosecution and police authorities are in charge. According to Article 20, para. 1 ACLA, the staff of Swissmedic and of the FCA who are entrusted with interrogations, inspections and coercive measures must be specially trained. Swissmedic has specific expertise in the field of medical products; should it require specific expertise in IT and financial matters, Article 90c TPA allows for external specialists to be called in as assistants for the safeguarding, evaluation and storage of extensive electronic data stocks. The FCA already has the specialist knowledge required by the Convention in the field of financial investigations and IT, as well as in the securing of assets and electronic data. The cantonal prosecution and police authorities as well as fedpol can rely on their experience in the field of narcotics, since the investigation methods used are similar to those in the medical products sector. The cantonal authorities may also consult the cantonal health authorities, if necessary. Additionally, the Ordinance on the Notification of Cantonal Criminal Decisions requires the cantonal authorities to inform (i.e. supply with a copy) Swissmedic about their criminal decisions based upon the TPA (cf. Article 3 No. 15). Swissmedic for its part has the right to appeal these decisions based on the assessment that the TPA has not been applied correctly (cf. answer 1).

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)

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;

Answer 29a:

Which investigation body takes responsibility for investigations of counterfeit medical products depends on the criminal jurisdiction to prosecute the case. The Swissmedic Penal Division is responsible for prosecuting perpetrators of violations relating to the manufacture, supply (i.e. import and export) and trafficking of counterfeit medical products, whereas violations in connection with the use and dispensing of counterfeit medical products fall under the jurisdiction of the cantonal prosecution authorities. If the import/export of counterfeit medical products also involves a violation of the Customs Act or the Value Added Tax Act, the FCA will prosecute and judge the offences (cf. Article 90, para. 1 TPA). The TPA provides for the possibility of combining the proceedings under either federal or cantonal jurisdiction if both federal and cantonal jurisdiction applies in a criminal matter that falls within the scope of the TPA's application (cf. Article 90, para. 4 TPA).

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).

Answer 29b:

There are no different processes or arrangements in place with relation to a pandemic.

Question 30. (optional)

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

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?

Answer 31:

Yes, reports on counterfeit medical products and similar crimes are collated on a national basis. Swissmedic maintains databases of reports regarding counterfeit medical products and

similar crimes. Records of investigations and measures are kept. If a local authority is dealing with a case of a crime regarding a medical product in their own jurisdiction, the case will be reported to Swissmedic, too.

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)?

Answer 32:

Yes, all offences described in the Articles 5-9 of the Convention 9 are investigated. As mentioned above (cf. Question 27 letters (b)-(e) and the answers thereto), the TPA does criminalise the manufacture, supply and trafficking of counterfeits, the falsification of documents and the commission of similar crimes involving threats to public health. With regard to Article 9 of the Convention, the attempt to commit criminal offences under the TPA and ”participation in” (aiding or abetting or inciting) such offences are punishable under Swiss law with regard to felonies and misdemeanours pursuant to Articles 22, 24 and 25 of the Swiss Criminal Code (SCC). Art. 86 TPA, by which the Convention has been implemented, specifies misdemeanours in para. 1 and felonies in paras. 2 and 3. The prosecution of these offences does not depend on a complaint as they protect public legal interests (“public health”), whereas under Swiss criminal law, only offences protecting individual legal interests may be subject to a complaint being lodged. Therefore, in the area of crimes involving threats to public health, criminal prosecution is governed by the “formal principle of legality”, meaning that law enforcement authorities are obliged to initiate an investigation if they become aware of or receive indications of the existence of such an offence.

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)?

Question 34. **(optional)**

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

Sanctions and aggravating circumstances

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

Question 35. (mandatory)

Do internal laws permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8? (Article 12. 2. a and b).

Answer 35:

Yes, as the SCC provides for these measures. Pursuant to Article 69, para. 1 SCC, the court shall order the forfeiture of objects that have been used or were intended to be used for the commission of an offence or that have been produced as a result of the commission of an offence in the event that such objects constitute a future danger to public safety, morals or public order. The court may (also) order that the objects forfeited be rendered unusable or be destroyed (Article 69, para. 2 SCC). These provisions are applicable regardless of whether the investigation is conducted by Swissmedic or the FCA based on the ACLA (cf. Article 2 which renders applicable the general provisions of the SCC) or by the cantonal prosecution authorities based on the CrimPC.

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?

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?

Answer 38:

The circumstances referred to in Article 13 of the Convention must be taken into account by the Swiss courts under Article 47 SCC. In the event of circumstances according to Article 13, letter (a) (endangerment of life and health), the penalty under the SCC is determined according to the severity of the violation. The abuse of trust according to Article 13, letters (b) and (c) indicates that the perpetrator acted with special knowledge and volition, which must be taken into account when assessing the penalty under Article 47, para. 2 SCC. The use of opportunities for large-scale distribution (Article 13, letter (d)) speaks in favour of the intention to conduct business on a large scale and thus endanger a large number of people. This is also an element that increases fault under Article 47, para. 2 SCC. The commission of the offence within the framework of a criminal organisation (Article 13, letter (e)), constitutes an offence in itself, which can be taken into account as an aggravating factor when determining the "concurrence of laws" (Article 260ter SCC). Repeated offences (Article 13, letter (f)) have always been taken into account in the assessment of penalties under Swiss law, cf. Article 47, para. 1 SCC. The occurrence of the offence during a pandemic is not generally considered an aggravating circumstance. However, if the perpetrator takes advantage of the pandemic or the offence is connected to the pandemic in other ways (e.g. production of falsified vaccines in large quantities which are then administered to the population), this may have a negative effect on the culpability of the perpetrator which is (also) assessed according to the reprehensibility of his/her conduct (cf. Article 47, para. 2 SCC).

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).

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.

List of abbreviations
(Switzerland's reply to the Questionnaire for the 1st thematic monitoring round)

ACLA	Federal Act on Administrative Criminal Law of 22 March 1974 French version: https://www.admin.ch/opc/fr/classified-compilation/19740066/index.html English version: not available
CrimPC	Swiss Criminal Procedure Code French version: https://www.admin.ch/opc/fr/classified-compilation/20052319/index.html English version: https://www.admin.ch/opc/en/classified-compilation/20052319/index.html
FCA	Federal Customs Administration https://www.ezv.admin.ch/ezv/en/home.html
fedpol	Federal Office of Police https://www.fedpol.admin.ch/fedpol/en/home.html
IMAC	Federal Act on International Mutual Assistance in Criminal Matters of 20 March 1981 French version: https://www.admin.ch/opc/fr/classified-compilation/19810037/index.html English version: https://www.admin.ch/opc/en/classified-compilation/19810037/index.html
OAG	Office of the Attorney General of Switzerland https://www.bundesanwaltschaft.ch/mpc/en/home.html
SCC	Swiss Criminal Code French version: https://www.admin.ch/opc/fr/classified-compilation/19370083/index.html English version: https://www.admin.ch/opc/fr/classified-compilation/19370083/index.html
SPOC	Single point of contact

List of abbreviations
(Switzerland's reply to the Questionnaire for the 1st thematic monitoring round)

Swissmedic	Swiss Agency for Therapeutic Products https://www.swissmedic.ch/swissmedic/en/home.html
TBTA	Federal Act on Technical Barriers to Trade of 6 October 19953 French version: https://www.admin.ch/opc/fr/classified-compilation/19950286/index.html English version: not available
TPA	Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (Therapeutic Products Act; SR 812.21) French version: https://www.admin.ch/opc/fr/classified-compilation/20002716/index.html English version: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html
VSA	Federal Act on Victim Support of 23 March 2007 French version: https://www.admin.ch/opc/fr/classified-compilation/20041159/index.html English version: not available